Veterans Administration

Rehabilitation R&D Progress Reports - 1984

Department of
Medicine and Surgery
Rehabilitation R&D Service

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Information for Principal Investigators
Providing Progress Reports for Future Issues

We welcome contributions to Rehabilitation R&D Progress Reports. It is our desire to present a comprehensive view of research and progress, and we do not want significant work to be omitted.

Reports intended for future issues must be received at the Office of Technology Transfer in Washington, D.C., in final form suitable for publication and ready for typesetting, by June 1 of each year. This will allow October mailing of future issues, as planned. It is hoped that contributing agencies and principal investigators will mark June 1 on their calendars as an ongoing, routine report period.

The text should contain a brief version of the research hypothesis, methodology, and preliminary findings and/or results since the last report. If the project is not completed, a brief comment on future plans or goals is appropriate. However, the entire report may not exceed 600 words. These reports are not meant to be, nor will they be handled as, short research papers. The goal of this progress report publication is to facilitate access to sources of information, formal or informal, about scientific research and engineering development, both completed and ongoing. The progress reports will not be refereed and their contents will be solely the statements of the investigators.

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1. Type letter-quality, double-spaced on 8½ × 11 inch paper.
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3. Include investigator(s) name(s) with highest degree, position, organization, and location (full address and zip code of principal investigator).
4. Clearly indicate on the first page the source(s) of funding for the work described in the report and the location(s) of the actual research activity.
5. Number the pages visibly.

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Rehabilitation R&D Progress Reports 1984

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A similar "Availability Announcement" will also be mailed for future issues of the Journal of Rehabilitation Research and Development. Those announcements will include a 10-year list of available back-issues (with prices) for the former Bulletin of Prosthetics Research as well as for Journal back-issues.

Editor's Note:

This is the second yearly issue of the Rehabilitation R&D Progress Reports. The series seeks to present an annual comprehensive overview of work in progress in the field of rehabilitation research and engineering both in this country and abroad.

Several improvements in format and organization have been made in this issue. These changes will make the information in this publication easier to use by allowing readers to quickly locate research of a particular nature. Project reports are categorized into 14 major subject headings: Amputations and Limb Prostheses; Orthotics; Total Joint Replacement (and other Orthopaedic Implants); Spinal Cord Injury; Functional Assessment; Biomechanics; Wound and Fracture Healing; Properties of Muscle; Ligaments and Tendons; Arthritis; Low Back Pain; Respiration (Muscular Dystrophy); Sensory Aids; and, Miscellaneous.

Following the progress reports are brief descriptions of the general research activities conducted by sponsoring agencies and organizations. Included in each agency/organization entry is a list of projects sponsored over the past year and the subject heading where they will be found.

The third section is an index of contributors. Names are listed alphabetically along with the page number(s) on which their contributions are located.

For the 1985 edition of the Rehabilitation R&D Progress Reports greater comprehensiveness in coverage of rehabilitation research and engineering developments is planned. All readers are urged to send progress reports by June 1st of this year in the format specified in Information for Principal Investigators Providing Progress Reports for Future Issues, located on page ii.

On the cover:

A graphic representation of the VA SEATTLE foot, a new prosthetic foot developed in the VA Rehabilitation Research and Development Program in Seattle, Washington. The design illustrates the internal keel, which improves the storage and release of gravity generated energy throughout the weight-bearing phase of the gait cycle. A progress report on the VA SEATTLE foot is on page 5.

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Rehabilitation R&D Progress Reports 1984

I. Amputations and Limb Prostheses

A. General

Comprehensive Management of Upper and Lower Extremity Amputation

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Plan—The purpose of the project is to continue to define the use of Xenon-133 for amputation level selection; to develop techniques for building inexpensive, rapidly fabricated, temporary prostheses; to evaluate the role of immediate postsurgical fitting for upper extremity amputation; and to investigate the role of elective amputation for patients with neurologic dysfunction.

Methods—Amputation level selection is performed using intradermal Xenon-133, the laser doppler, and doppler ankle systolic blood pressure measurements. Prostheses are provided at the time of surgery, and all patients are fitted with temporary lightweight prostheses which are modified as needed until the patient is eligible for a permanent prosthesis. Patients undergoing upper extremity amputation in the Tucson VA Medical Center, the University of Arizona HSC, the Atlanta VA Medical Center, and Emory University were pooled into one group to evaluate the role of immediate, early, and late prosthetic fitting after upper extremity amputation. Finally, elective amputation with subsequent prosthetic fitting was evaluated in a group of patients with neurologic dysfunction due to brachial plexus injuries.

Results—

1. Intradermal Xenon skin blood flow continues to have greater than 95 percent accuracy for prediction of healing at all levels of lower extremity amputation and continues to be superior to the laser doppler or doppler ankle systolic pressures. In addition, our Xenon work has been validated by the University of Cincinnati.
2. Our results on immediate postoperative fitting for upper limb amputation demonstrate that there is a 30-day grace period for early or rapid fitting after which the success rates of rehabilitation decline dramatically.
3. For patients with non-reconstructable brachial plexus injury, elective amputation with shoulder fusion, and early or rapid prosthetic fitting is an excellent rehabilitation tool.
4. Fiberglass casting tapes and PVC plastic pipe can be combined to build easily fabricated, lightweight, inexpensive, temporary prostheses, which allow evaluation of patients with marginal rehabilitation potential, continued rehabilitation of patients who are already ambulatory, or economic fabrication of permanent prostheses for patients with limited financial resources.

During the last year, this research program has resulted in 9 publications, 5 audio-video tapes, and 22 presentations at national meetings.

Future Direction and Efforts—The areas that our program is moving toward include biomedical research and closer ties with the College of Engineering at the University of Arizona; patient education; teaching, both at a regional level and to appropriate referral hospitals; evaluation of new prosthetic components; evaluation of limb sparing or salvaging techniques which might obviate the need for upper and lower extremity amputation; and continued comparison and evaluation of Xenon-133 with other methods of amputation level selection■

Successful Application of CAD Automation to the Production of Individual Prostheses

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Sponsor: University College London

Background—The first step along the path to computerized, automated socket and prosthesis production was taken several years ago, when the Rapidform technique for automatically fabricating thermoplastic sockets was developed and brought into service. Those sockets were the first thermoplastic sockets in clinical service in the United Kingdom and they have proved to be highly successful. They are accurate, hygienic, extremely tough, slightly resilient, and very reliable. In fact, there have been no mechanical failures of any socket—and some have been used regularly by patients for over 6 years. These sockets are fabricated very rapidly, and they are very inexpensive to produce. The Rapidform machines form consistent high-quality sockets without the need for a skilled operator. The United Kingdom Government's Central Office of Information (COI) made a film of the process about 4 years ago. It is entitled "Fit A Limb" and was part of the Living Tomorrow series. The United Kingdom Department of Health and Social Security provisioned Rapidform machines for their Limb Centres, and private purchases were also made by certain major limb manufacturing firms. There are many thousands of patients now fitted with Rapidform sockets, including a number of patients of one Arab country. More recently, the Rapidform sockets became available in Canada through the University of British Columbia (UBC).

The successful development of the Rapidform socket fabrication system was followed by a semi-automated system for rapidly and cheaply fabricating a type of below-knee prostheses called Tapered Column Prostheses. This technique fabricates thermoplastic shin sections by rotationally casting the required section in a specially controlled machine. No operator skill is required. The tapered columns are extremely lightweight and strong. They interface via plastic alignment couplings at either end to the socket and the foot. These sections are fabricated quickly and very cheaply. A typical below-knee prosthetic system comprising a Rapidform socket, tapered column and alignment couplings, and a SACH foot weighs just under one kilogram. The system has an exceedingly good fatigue life. An above-knee system is being finalized.

The fabrication of the socket requires a model that represents the rectified shape of the stump. The usual techniques were considered inadequate, and a joint project was carried out with the Medical Engineering Resource Unit of UBC which evoked a computer-aided design system for defining the required stump shape. The rectification is carried out with reference to a video display and is stored in the computer memory. The result is a set of coordinates that define the required shape of the interior of the socket. The Bioengineering Centre designed and built a cheap, rapid, and accurate computer-numerical-controlled (CNC) machine that uses this coordinated data to cut and shape a wax blank. This carved wax blank is the model of the rectified stump shape over which the thermoplastic socket is then Rapidformed.

In Less than 2 Hours at Low Cost—The computer-aided-design (CAD) shape definition system typically takes 10 minutes to define the required shape (using a few key measurements taken from the patient). The CNC machine then takes about 10 minutes to produce the model representing the stump shape. This is used in Rapidform to fabricate a socket in 20 minutes. In parallel with this socket preparation, the shin section (tapered column) is rotationally molded.

A patient can be measured and fitted with a prosthesis within a very short timescale—typically less than 2 hours even with trimming and adjusting. Because of the low cost and high speed of the process, it is considered preferable to manufacture and issue a new prosthesis than to undertake repairs■

Effectiveness of Prosthetic and Orthotic Devices Used in Pakistan

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Sponsor: National Institute of Handicapped Research

This project's objectives were to determine the effectiveness of prosthetic and orthotic devices presently in use in Pakistan, and to determine the kinds and frequency of disability in the geographic area of the research effort.

Methodology—The project has been spread over 4 years, with the fifth year being used to evaluate all the collected data.

Each year 20 handicapped persons were chosen

from each disability category and evaluated individually from medical, psychological, and social or prosthetic/orthotic aspects. They were then fitted with either a standard or experimental device under supervision of a physician, prosthetist, social worker, and physiotherapist, and allowed to return to their normal environments.

The evaluation team examined the participating patients at least twice a year, and necessary modifications were made. Detailed records were kept. At the end of the study period it should be possible to determine the merits and deficiencies of the so-called modern prosthetic/orthotic devices as compared to more conventional devices.

Currently, final data collection is in progress and a critical review of all project activities is being carried out prior to preparation of a final report.

Preliminary Findings—Perhaps because of the peculiar climatic conditions, we find that above-knee sockets made of synthetic materials cause far greater problems than wooden ones. The modified Geisenger foot developed at the centre had to be further modified, with the deletion of the anterior rubber wedge, as it had an unacceptable incidence of breakdown.

The peg leg has still a place in the management of an above-knee amputee, as it gives complete freedom of movement in the manual worker.

Bonding agents are still a problem, with some solidifying in their containers even before delivery to the centre. Others show a marked tendency to bond with less strength and cause the parts to come apart, particularly during hot and humid temperatures which are characteristic of the summer months.

The below-knee amputee has been the most satisfied patient, as the modern PTB (patellar tendon bearing) prosthesis has revolutionized the patient's life. It has found universal acceptability and patients manage to do their fairly demanding manual jobs without many problems. In contrast, there has been little progress in pleasing the upper limb amputee. The locally fabricated mechanical hand has had a very high failure rate, and we have no access to myoelectric devices.

On the orthotic side, the high incidence of poliomyelitis and its devastating effects have been highlighted in our previous report. A nationwide preventative program is in progress, effects of which may be evident in the next 4 years.

Light alloys for the construction of calipers and various assistive devices, which should be easy to work with, are very much needed. We find that the aluminum alloys currently available are highly susceptible to metal fatigue and breakage.

Psychological Aspects—It has been possible to help most of our patients to readjust themselves to their handicaps. Most have been rehabilitated to reasonable employment; a few have continued on their original jobs. The most maladjusted are the upper limb amputees, for reasons mentioned above.

The centre was pleased to receive Mr. G. A. Engstrom of the National Institute of Handicapped Research for a review of our project activities in the summer of 1983.

Evaluation of the Effectiveness of Modern Prosthetic/Orthotic Techniques and/or Hardware in Pakistan at King Edward Medical College

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Sponsor: National Institute of Handicapped Research

The project was started with the aim of investigating regarding the frequency of various types of disabilities, to examine their causes, and to evaluate in a phased way the modern prostheses and orthotic techniques in rehabilitation of the patients with their own peculiar social and cultural customs. It was started in January, 1979, and the following phases were earmarked:

1. Rehabilitation of below-knee amputees;
2. Rehabilitation of above-knee amputees;
3. Rehabilitation of upper limb amputees;
4. Rehabilitation of patients requiring lower limb orthoses; and
5. Rehabilitation of amputees requiring upper limb orthoses.

The initial phase of the project was conducted in an improvised workshop in the old hospital building, but now the work is being done in the new, fairly well equipped and well staffed Orthopædic Workshop Building.

At present, we are beginning phase 3, and this report covers our experiences in the first two phases.

Twenty patients with below-knee amputations were fitted with a-patellar tendon bearing (PTB) prostheses. The component parts were custom-made and plaster of Paris model of the amputation stump was used for initial fabrication of socket. Basically a leather socket with a rubber lining was used which was hardened on external surface by application of layer of araldite and

hardener. An effort is made to give the surface of the socket a color matching the patient's skin color. The willow wood shin piece is mounted on a SACH foot that is made here.

The below-knee amputees included 12 adult male patients (one of them with a bilateral amputation), 5 adult female patients, and 3 children (one girl and two boys). Eight of these patients had amputation following road traffic accidents, two resulted from war injuries, and two others suffered blast injury from a minefield. Four patients had amputation following infection, and four were congenital amputations. The patients had a variety of occupations, both active and sedentary. The residual limb sizes among adult patients ranged from 3¼ inches to 10 inches. The youngest patient was 2-years-old and the oldest was 70 years.

An elaborate examination of the prostheses and the patients was made before final checkout and gratifying experiences have been recorded. However, congenital amputees and amputation among those young in age tend to show the best rehabilitative results in terms of routine activities, including active sports. The sockets prepared with araldite have proved quite satisfactory; they are light in weight and strong.

In phase 2 of the project, 40 patients with above-knee amputations were registered, including 1 bilateral. The youngest was a child of 6 and the oldest was 65. Thirty-three were adult males and seven were adult females. Their occupations ranged from school teacher, housewife, and blacksmith to cart or rickshaw driver, tailor, shopkeeper, student, and soldier. The reasons for amputation were as wide-ranging as had been the case with the below-knee amputation group: malignancy, infection, road accidents, war, industrial accidents, and homicidal attempts were recorded. Residual limb lengths among the adult patients ranged from 8 cm to 32.5 cm.

Typical of the above-knee prosthesis used was one with a wooden anatomically shaped socket with rubber lining, mounted on a wooden thigh piece and shin piece joined by a hinge at the knee. The knee joint is fitted with a manual lock. The foot-ankle assembly is the same as that used with the PTB prostheses.

At present, suspension for the above-knee prosthesis is supplied, through a hip hinge joint, by a pelvic belt. Arrangements are being made to develop suction sockets in the near future.

Initial results of the prostheses used have been quite satisfactory. Long-term results will be evaluated in the final phase of the project■

[See also **VII. Wound and Fracture Healing**, Morphological and Clinical Studies of Microwounds in Ischemic Human Tissues, and Transcutaneous Oxygen Tension as Predictor of Wound Healing]

B. Lower Limb

1. General

Automated Fabrication of Lower Extremity Prosthetic Sockets

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Our study is a demonstration of the feasibility of applying computer-aided-design (CAD) and computer-aided-manufacturing (CAM) technologies to the design and construction of prosthetic sockets. Briefly, the process involves quantifying the shape of the unloaded stump, defining the mechanical properties of the residual limb, e.g., modulus and density, and using these data as input for a finite element analysis of the limb to predict what the socket shape should be so that the loads are distributed over the surface of the stump in a manner that accounts for load sensitive areas. The output of the analysis is then used to drive a numerical control cutter that shapes the socket mold.

During this report period, January 1, 1984, through April 30, 1984, our efforts have been focused in four areas.

The first has been collecting data about the economic feasibility of using CAD/CAM technologies to produce sockets. Specifically, we have been collecting information to help answer the following questions. What are the economic dimensions of the existing system? Given the limits of production and product price limits, can the proposed system be profitable? What is the likely impact of the proposed system on those who presently provide prosthetic services?

The second activity area has been to develop an automated shape-sensing instrument that provides sufficient sensitivity and is simple and quick to use. The instrument has been designed to collect the necessary data in 5 minutes or less, depending on the size of the residual limb, and a prototype is nearing

completion with clinical trials of the sensor scheduled for June, 1984.

Most of our effort has been spent on developing the instrumentation that is required to characterize the mechanical properties of the soft tissue composing the residual limb. An ultrasonic system has been designed to define the tissue properties and the internal structure, i.e., the location of the skeleton within the soft tissue mass. The device consists of three range-gated doppler transducers that are used to measure the internal displacements of the tissue that result from the application of an external cyclic mechanical perturbation of the tissue.

The fourth set of activities has focused on selecting a finite element code that can be used in an interactive manner. A version of ANSYS has been selected and we are currently working with Swanson Analysis System, Inc., and CDC to develop the software that we will need to make the program friendly and usable in a clinical setting.

Our preliminary findings indicate that the results of the project promise to enhance the feasibility of using central fabrication facilities within the VA service delivery system and thus increase the system's capacity and ability to continue high quality care to the growing population of amputees.

[See also **XIV. Miscellaneous**, A Program for Evaluation and Monitoring the Dysvacular Patient]

The VA SEATTLE Foot

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Research and evaluation continue at this facility on the VA SEATTLE foot, a prosthetic foot created to improve the storage and release of gravity generated energy. Conceptually, the foot is designed to improve energy storing throughout the weight-bearing phase of the gait cycle. This energy is then progressively released as the foot continues through toe-off to rebound and propel the body forward. The kinesiology data used to arrive at the materials and engineering design were obtained under a Veterans Administration contract to conduct a comprehensive study of the development and improvement of running skills in unilateral below-knee amputees. These studies extended over a three year period terminating in June of 1984. (Doris I. Miller, Ph.D., Michael W. Passer, M.D., and Ernest M. Burgess, M.D., were co-investigators.) The studies were conducted at the Department of Kinesiology at the University of Washington in Seattle, the Prosthetics Research Study, and the VAMC, Seattle, Washington.

The resultant joint torque patterns determine the mathematical specifications for design and materials used in the keel of the VA SEATTLE foot. A wide variety of synthetic and composite materials were tested. Simplicity of design, durability, and cost effectiveness were considered together with the force/deflection patterns needed. The foaming of the keel was initially in the general shape of a foot and suitable for shoe fitting. This shape corresponded to the one generally used in commercially available prosthetic feet. As design progressed, anatomical models were prepared so the foot would actually resemble a natural foot for those people who preferred this type of cosmesis.

At this time, the keel design and the cosmetic cover have been standardized. Bench testing has included a thorough force/motion study of all parameters of performance together with breakage, fatigue, and endurance studies. In addition to these bench tests carried out at the Prosthetics Research Study and in contract facilities, the foot has been tested at the Army laboratories, NATICK, Massachusetts. Gait research continues also in our facilities and in other established gait laboratories.

The outstanding acceptance of this component by users encourages us to recommend its broad use in the large majority of adult lower limb amputees. The VA SEATTLE foot is ready for commercialization and general availability. Data gathered from the 550 amputees who have been wearing the foot for varying periods of time over the past 3 years are being compiled by the Evaluation Unit of the Rehabilitation Research and Development Service at the Veterans Administration Central Office in Washington, D.C. The Prosthetics Research Study will continue to improve and refine the concept that has resulted in the successful development of the VA SEATTLE foot.

2. Below-Knee

Volume Changes Occurring in Postoperative Below-Knee Amputees

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

A frequent problem occurring during the rehabilitation of postoperative amputees is how to determine precisely when the stump is ready to be fitted with the first permanent prosthesis. Inaccurate estimates often lead to ordering a prosthesis at a time when the stump volume is still changing. This results in stump-socket disparities, often the cause of pain and skin breakdown, necessitating a new prosthesis.

Hypotheses—The hypotheses in this study are the following:

1. Factors can be determined that point to the most efficacious method, among a choice of three, for achieving early maturation of stumps in recent below-knee amputees.
2. A method can be found to determine and define the stabilization point in the maturation of a stump for the purpose of choosing the proper time to fit the first permanent prosthesis.
3. The service life of the first permanent prosthesis can be extended through more precision in stump management techniques and choice of time to fit the prosthesis.

Methodology

Sample Size—A target of 20 subjects in each of three categories of stump reduction methods:

a. elastic wrap;
b. plaster cast and pylon; and
c. plastic laminate and pylon.

Measurements—Measure volume of the stump using a water displacement method, measure stump circumferences at 2, 4, and 6 inches from the distal aspects, measure circumference of contralateral calf, and record weight. These measurements are made weekly (Phase I), until fitting of first permanent prosthesis, then bimonthly for duration of first permanent prosthesis (Phase II).

Criteria for Stabilization Point—Initially an arbitrary stump-volume change rate was chosen as the criterion—that is, when the rate of change reached 1.0 ml/day, the stump was declared stable. Based on the success of that criterion during the first 2 years of testing, correlates were determined and incorporated into the study as additional criteria are mentioned in the findings.

Preliminary Findings

Subject Performance—Forty of the target number of 60 patients have completed the pre-prosthesis phase (Phase I) of the study, and are distributed nearly equally among the three stump treatment methods. Only about two-thirds of the patients enrolled in the study completed Phase I. Further, a total of 14 subjects who completed Phase I did not enter Phase II. The drop outs occurred for a variety of reasons, such as moving away, stump healing problems, further surgery, disinterest, and death. A total of 10 subjects are currently being monitored during the use of their first permanent prosthesis (Phase II). Three subjects were discontinued from Phase II, two for looseness of fit at 8 and 9 months, respectively, and one when it was necessary to amputate the contralateral limb. One subject has worn the first permanent prosthesis for over 3 years; four have been monitored for over 2 years; two have been monitored for over 1 year; the three more recent entrants into Phase II have been monitored for less than a year.

Volume vs. Time—Approximately one-half of the subjects showed a clearly defined decline in stump volume as a function of time. The balance did not. Interestingly enough, the two subjects demonstrating looseness of fit in Phase II were among those not showing a decline in stump volume.

Correlation of Circumference with Volume—A high correlation exists between circumference measured at 2 and 4 inches from the distal aspect. In most cases the correlation is significant at the $p = 0.01$ level or better.

Stabilization Criteria—When stump volume and circumference relate to time during maturation, the decrease is logarithmic with time. A line of regression or curve of best fit can be drawn through the data. At the onset of the study, stabilization was declared when the rate of change of volume reached 1.0 ml/day. Because of the relative success of this, other relations have been incorporated to supplement the original criterion. These include percent change in volume and circumference: 20 percent reduction in volume, and 15 percent and 9 percent reduction in circumference at 2 and 4 inches, respectively.

The average time to reach the stabilization point is about 65 days. Those patients not showing a decline

in volume were fitted with their prosthesis after 70 days.

Stump Reduction Method—To date, no clear distinction has been shown between the method stump reduction and performances in Phases I and II. However, the results may be somewhat skewed. Philosophically, the individuals were patients first and test subjects second. All patients were not considered equal candidates for each of the categories. Moreover, half of the subjects showed no definable decrease in stump volume as a function of time regardless of the category to which they were assigned. Currently, no trends are seen.

Future Plans—The foremost goal is to incorporate at least 20 more subjects into the study to increase the reliability of results.

Optimum Prosthetic Foot Characteristics for Dysvascular Below-Knee Amputees

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Hypothesis—Below-knee amputee gait can be optimized by adjusting the heel firmness and keel length of the SACH or SAFE prosthetic foot.

Method—To study the effect of varying prosthetic foot heel compressibility and prosthetic foot keel length on velocity, stride length, single support time, cadence, heel dwell time, EMG, joint torques, and dynamic heel compression.

Goal—To reduce skin breakdown in dysvascular patients, decrease compromise of cardiac, respiratory, and musculoskeletal systems by improving energy expenditure and reducing unwanted pressure over the anterior tibia inside below-knee prostheses.

Analysis of Below-Knee Suspension Systems: Effect on Gait

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

It is well known that the main purpose of a given suspension for a below-knee prosthesis is limb retention, but the specific effects on other areas of stump-socket biomechanics are not as obvious. A factor, such as restrictions of knee range-of-motion either by suprapatellar or supracondylar socket enclosure, not only imposes specific effects on life style, but also imposes effects on gait patterns and on locomotory work expenditure. In addition, certain suspension modifications designed to minimize axial stump-socket movement may alter the basic biomechanical principles of the prescribed prosthetic device. What emerges from clinical observations is the need for guidelines and specific prescription criteria for specific suspension systems.

Key Questions—The key questions expected to be answered through this study are:

1. What are the specific prescription criteria for a suspension system for a given patient?
2. How does patient activity level affect the choice of a suspension system?
3. How do stump characteristics and physical capability affect the choice of a suspension system?
4. What gait variables, measured or derived, are useful to differentiate effects on gait resulting from different suspension systems?
5. What gait variables, or combinations of variables, serve to discriminate relative effectiveness of a given suspension system?
6. What are the advantages and disadvantages of a given suspension system?

Methodology—Test 20 unilateral below-knee amputees in the age range of 40 to 65 years. Each will be tested with the following seven suspension systems: (i) supracondylar suprapatellar, (ii) supracondylar, (iii) PTB cuff, (iv) PTB cuff with waist belt, (v) PTB cuff with figure-eight suprapatellar strap, (vi) rubber sleeve, and (vii) articulated supracondylar wedge. The plan employs one PTB-type prosthesis, altered successively in the order listed. Each subject is expected to wear the test prosthesis at least 2 hours per day between weekly test appointments.

The subjects are instrumented with bilateral heel and toe switches, bilateral knee electrogoniometers, an axial stump-socket movement detector, a gimbal mounted triaxial accelerometer mounted at the sacro-lumbar area, and a cord connected to a stationary tachometer. The subjects are instructed to walk at three different speeds: (i) comfortable, (ii) faster than "comfortable," and (iii) slower than "comfortable." The purpose of the fast and slow speeds is to provide challenges to the systems.

In addition to treating the collected data to the commonly used gait variables, mechanical work of locomotion will be calculated together with an efficiency figure representing the effectiveness of transfer between potential and kinetic energies. The axial movement of the stump in the socket will be analyzed for amplitude and for when in the gait cycle the signal occurs. Wave forms of the accelerometer and tachometer will be treated for harmonic ratios. Deviations in the knee, accelerometer, and tachometer wave forms will be identified and correlated to the suspensions. This scheme of testing will allow comparative biomechanical analyses within each subject and a basis for comparison among subjects to ascertain the effect on gait by the seven suspension systems■

Evaluation of Physiologic Suspension Factors in Below-Knee Amputees

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Functional capacity in below-knee amputees relate directly to the accuracy of the prosthetic fit. Prosthesis suspension is necessary to maintain this accuracy throughout the gait cycle. Ancillary mechanisms, suction, and physiologic mechanisms contribute to prosthesis suspension.

Hypotheses

1. Below-knee amputee function can be improved by effective utilization of physiologic capabilities specific to muscle stabilized residual limbs.
2. The degree of this capability is clinically assessable.
3. Specific socket guidelines are necessary to achieve physiologic suspension.
4. Training within the prosthesis socket is an effective method for improving physiologic suspension.

Project Objectives and Methodologies

1. Create apparatus, measurement techniques, and a data base for below-knee amputee physiologic suspension parameters and performance. Establish techniques for clinical prediction of physiologic suspension capability.

A. We have built force/displacement, surface and subsurface contour and dimension, and stump and socket volume measurements apparatus.

B. We evaluate physiologic suspension potential clinically by determining how much weight the amputee can lift with the prosthesis without using ancillary suspension.

C. We have measured suspension factors and suspension performance in 60 definitive and 30 research prostheses.

2. Establish guidelines for optimal prosthesis design. Our socket design guidelines include:

A. Distal m-1 measurement of the residual limb at the apex of the muscle bulge with the stump musculature contracted. VAPC calipers are used to provide appropriate tissue compression.

B. A measurement of axial skin looseness.

C. Premodified casting using thixltropic water clay.

D. A vacuum casting technique.

E. Casting with the residual stump musculature contracted.

F. Careful molding and replication of the flares of the tibia. A radical PTB bar with the associated high popliteal pressures and deep anterior tibial relief is replaced by anatomical configurations and a selective liner.

G. Distal molding of the skin and soft tissue during casting and use of a pull in liner (for suction and nonsuction fits).

H. 5-10 percent tissue compression by the prosthesis (approx. ¼″ tension).

3. Develop a technique by which the amputee can train the stump musculature for physiologic suspension. We have established a protocol using ankle weights to train for physiologic suspension within the environment of the prosthetic socket.

4. Correlate differences in performance between trained and untrained groups of amputees by applying multiple regression analysis technique to suspension factors. This analysis indicated that we were not measuring all of the relevant factors for physiologic suspension or that the sample size was too small. Volume measurement was not included. Definitive correlations could not be established.

Accomplishments—We have made two prostheses as described above during this period and project more for high performance amputees. Our training protocol continues to be followed by two or three wearers.

Despite continued work, the volume device is still hung up at the Timex computer interface.

We have established a retention evaluation protocol using ankle weights and a flexed knee.

During this reporting period we have presented this research at a regional meeting of the AAOP. Three more presentations, including the AOPA and the UCLA advanced below-knee prosthetics course, are scheduled over the next year.

Our investigation has determined that 3-D CAD and digitization technology now offer microcomputer systems capable of providing complete display and analysis of prosthetic fit clinically. These systems would be upgradable for actual socket production.

Findings

1. Appropriate prosthesis design for physiologic suspension improves existing suspension; inappropriate treatment can allow these same muscles to eject the socket.
2. Research prostheses as described above are well accepted by the two amputees presently wearing them. Both can lift approximately five times the weight of the prosthesis by physiologic components alone. Subjects wearing limbs of our earlier configuration are able to lift approximately two times the prosthesis weight by physiologic components.
3. Amputees indicate that our training protocol improves and maintains the tone of their residual limb musculature. Evaluation of test and control groups showed statistically significant improvement in tensile retention force for the trained group.

Conclusions—Both potential for and function of physiologic suspension are easily evaluated in the clinic with our methods.

Physiologic suspension can improve the suspension of any below-knee prostheses where the residual limb offers some degree of purchasable contour and where the amputee is willing to train the musculature.

Our training protocol is an effective adjunct to physiologic suspension.

Maximum benefit from physiologic suspension is derived by suction suspension systems.

Real world application of these findings is limited by commercial constraints■

3. Above-Knee

Myoelectrically Controlled Above-Knee Prosthesis: A Pilot Study

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Problem Statement—The need exists for volitionally controlled above-knee (A/K) prostheses that are more easily controlled by the amputee. In the past, control of lower limb prostheses has been largely limited to preprogrammed, passive devices that are not easily controlled. Presently, the most popular means of passive control is the use of fluid damping mechanisms at the knee joint. Passive damping control can only be made appropriate over a limited range of gait and does not provide for active movement of the prosthesis. Active control of the prosthesis permits continuous adjustment to changing gait conditions, decreasing metabolic energy usage, and the ability to respond to extraordinary events, such as stumbling.

A myoelectrically controlled pneumatically operated above-knee prosthesis has been developed at this laboratory that provides greater conscious and subconscious active control in gait and nongait activities for the above-knee amputee. The specific questions being explored during the pilot study are:

1. Can the observed limitations of the current myoelectrically controlled pneumatically operated prototype actuator, which utilizes air as the only working fluid, be obviated by replacing air with an incompressible hydraulic fluid, and continue to employ pneumatic regenerated energy storage?
2. What is the nature of time-series methods and what are the advantages and disadvantages of multichannel processing for control of prostheses?
3. How long can an amputee maintain adequate control over the prosthesis with the static spatial pattern recognition system?

Methodology

1. **Controller Actuator Modeling Methodology**—Review current controller-actuator pneumatic prototype and dynamical equations.

Generate alternative controller-actuator hydraulic/pneumatic configurations.

Select promising controller-actuator hydraulic/pneumatic configurations.

Derive dynamic equations for the most promising hydraulic/pneumatic controller-actuator configurations.

Conduct simulations using new model.

2. **Methods for Time-Series Studies**—Define the most accurate time-series representation of the surface EMG, choosing from AR, MA, or ARMA filter structures of varying order.

Identify single and multichannel processor structures and algorithms.

Implement the processors in software to simulate their real-time operation and allow performances to be monitored.

Compare system performances.

Examine effects of electrode number and location on classifier behavior.

3. **Methods for EMG Pattern Study**—Measure the variation of patterns of processed EMG for identical tasks.

Determine if the EMG pattern classifiers exhibit a variation over time and the nature of its time course.

Measure the performance of the classifiers.

Preliminary Findings

1. **Modeling and Simulation**—A single accumulator hydraulic/pneumatic actuator system was modeled. Simulations are in progress at this time. A multiple accumulator system model is being prepared to study efficiency of energy cascading for the actuator.

2. **Time-Series Studies**—A Box-Jenkins analysis of the surface EMG from location on the posterio-lateral thigh intermediate to flexor and extensor musculature suggests that the signal is purely autoregressive and of low order, typically less than five.

The performance of single-channel, multiple-hypothesis-testing classifiers are inconsistent and often inaccurate.

Inclusion of spatially distributed information extends the operating range of time-series classifiers in terms of level of contraction.

The weighted sum of the squared residual errors increases nonlinearly with contraction level. Signal and residual variance is related to the state of tension of the underlying musculature.

Plans to expand the studies to include a larger population, to definitively specify the role of electrode location in the multichannel case, to quantitatively measure system performances in terms of operating range and response times, and to determine the relationship between residual variance and joint torque are being formulated.

3. **EMG Pattern Study**—Preliminary findings support rejecting the hypothesis of stationarity for processed EMG, patterns of EMG, and linear discriminant function (LDF) coefficients on the minute and hour scales. At any given instant of time, the data show no significant difference with that obtained 1 second later for the isometric/isotonic muscle states. The invariance of grand mean LDF coefficients over force and the proportionality of grand mean EMG patterns with force suggests that the spatial pattern recognition system may be an appropriate model structure for magnitude prediction.

The next step is to measure the classifier's performance over time in terms of percent correct classifier performance, minimum mean square error between predicted and actual actuator force (or knee moment), and response times. This work is currently in progress. The results to date suggest that an adaptive intent recognition system should be investigated■

Development of an Above-Knee Prosthesis Adaptable to a Voluntary Walking Period

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Sponsor: Waseda University

Disabled persons using conventional above-knee prostheses have not been able to walk with their voluntary walking period on level ground.

The most recent above-knee prosthesis, model WLP-6 (Waseda Legg Prosthesis-6) developed in our laboratory, has the following mechanisms for amputees to enable ambulation with any walking period according to intention:

1. A mechanism for automatically adjusting damping moment around a knee joint. A damper for depressing rotation of a knee joint consists of a pneumatic piston and cylinder and a needle valve which is adjusted by a DC motor.

2. A mechanism for generating a little driving moment for walking fast. Compressed air is accumulated by an air compressor which is activated by the rotation of an ankle joint during stance phase. In the subsequent swing phase, the compressed air is injected into the piston and cylinder of a knee joint to swing the prosthetic shank.

The weight of the below-knee prosthesis of WLP-6 is 2.3 Kg and the entire weight with socket is about 3.5 Kg. The plastic reinforced with carbon fiber is used in the structural part to lessen the weight.

EMG (Electromyogram) readings picked up from an amputated leg are used as signals that enable an amputee to voluntarily control WLP-6. EMG is picked up by a bipolar surface electrode, preamplified, treated with analog and digital filters, and summed its absolute values with real time for 0.1 second at the beginning of heel contact.

The prediction algorithm predicts the next step's walking period by using EMG data. Coefficients between EMG data and walking period in the prediction algorithm are always regulated by past EMG data and measured walking period data so that precise prediction is achieved and gain variation of EMG by tiredness and perspiration is neglected. The whole software treatment of EMG—digital filtering, summation, and prediction algorithm of the next step's walking period—was assembled into the tiny microcomputer unit (ZILOG z-8 one chip microprocessor).

The control sequence of WLP-6 by the microcomputer unit during one walking period is as follows:

1. EMG is analog to digital (A/D) converted, digital

filtered, and the summed absolute value for 0.1 second at the beginning of heel contact.

2. The predicted walking period of the next step is calculated with EMG data by the proposed prediction algorithm.

3. The rotational degree of the needle valve is adjusted by the DC motor according to the predicted walking period calculated. The procedures 1 through 3 are terminated within a stance phase (at least 0.6 second). In the same duration, compressed air is accumulated into the accumulator by rotation of the ankle joint.

4. At a timing of a transition from flexion to extension during a swing phase, accumulated compressed air is injected into the chamber of the piston cylinder of the knee joint by turning on the DC solenoid valve to generate a little extension moment around the knee joint.

The walking experiments by the amputees were performed using the developed WLP-6 system. The microcomputer unit and the battery were attached on the subject's back. The subject walked with his voluntary walking period. The results of those walking experiments were as follows:

1. The most suitable position of the electrode of EMG was M. adductor longus.

2. The proposed prediction algorithm of the next step's walking period was predicted within 10 percent of prediction error.

3. Subjects could walk with voluntary walking period of between 1.1 to 1.6 seconds. This walking period is almost the same as the one with which a normal person walks in daily life.

4. Subjects did not feel any burden by the weight of WLP-6 (2.3 Kg below-knee prosthesis)■

C. Upper Limb

1. General

Myoelectric Controls for Orthotic/Prosthetic Systems

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The investigator proposes to build a myoelectric controller consisting of an implantable electrode array, an implantable telemetric device, a receiver/decoder and a low-power myoprocessor. Its purpose will be to drive orthotic/prosthetic systems with the residual neuromuscular activity of the affected limbs. The telemetric device will be powered by radio frequency. All the electronic components of the system will be miniaturized. The implantable telemetric device will be hermetically sealed in a titanium capsule.

The electrode array already has been tested in animals. The prototype circuit for the four-channel telemetric device has been designed and is near completion. Miniaturization will involve use of CMOS and a number of semi-custom integrated circuit units. Commercially available implant packages will be used to house the electronics. The prototype receiver/decoder has been built and tested; the systems function as designed and are now being miniaturized■

Myoprocessor NU-110

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Sponsor: Northwestern University
Rehabilitation Engineering Program

The design work on the NU-110, a single-site signal processor with a single output, has been completed. In its final design, the same printed circuit board can be assembled as a controller for the Michigan Hook, the Hosmer Dorrance Prehension Actuator, or a Myoswitch by changing only a few components. The Myoprocessor with a NU-126 Myotrode has a total quiescent current of only 30 microamps at 6.25 volts. Because of the extremely low power requirements, an on-off switch is not necessary.

A manufacturer has contracted for an initial production run of 25 units■

Myoprocessor NU-112

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Sponsor: Northwestern University
Rehabilitation Engineering Program

The objective of this project is to develop a two-site signal processor to control a motor in two directions. This controller could be used with the NU Synergetic Hook and any commercially available electric hand.

Surface-mounted device (SMD) techniques will be used to build an extremely small circuit. This will facilitate fitting long below-elbow prostheses and children's prostheses.

The low power requirements will permit the use of smaller batteries. Four prototype processors have been constructed for trial fittings.

Myotrode NU-126

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Rehabilitation Engineering Program

Work on the active electrode package has been completed. The final design is a small molded unit enclosing the preamplifier, and shaped so as to be easily removed from a prosthesis. The unit contains two threaded inserts to allow the use of electrode buttons of suitable height. The cable can be replaced if broken or damaged. Cost of the Myotrode should be low enough to make it a nonrepairable, throw-away item.

A manufacturer has started an initial production run of 100 units. These will be used with the Myoprocessor for myoelectric control of the Michigan Hook and the Hosmer Dorrance Prehension Actuator.

[See also **VIII. Properties of Muscle**, Surface Electrode for Detecting Myoelectric Signals]

Long-Term Recording of Voluntarily Elicited Nerve Signals

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Sponsor: Liberty Mutual Insurance Company

We are developing a recording electrode unit that can easily be implanted around a severed nerve and that will continuously detect neuroelectric signals associated with functionally distinct limb movements. Our specific goal is that the neuroelectric signals will be transmitted externally to control a multiple-degree-of-freedom version of the myoelectric prosthesis, the Boston Elbow.

A recording electrode unit with these capabilities will also have countless other useful applications. When a neuroelectric signal associated with volitional intention can be made available outside the body, it may be employed to control any number of devices or appliances in the environment. Such a recording electrode has exciting prospects: it could revolutionize both our approach to rehabilitating physically handicapped individuals and the interactions of people in general with their environments.

In preliminary experiments with rabbits, several complications affected the time duration and the amplitude of the neuroelectric signal, but we have clearly demonstrated that long-term recording of such signals from the surface of severed peripheral nerves is feasible. We must now demonstrate that the signal is related to the animal's volition. Two experiments with trained subhuman primates had limited success. With a third primate, results were ambiguous and require further consideration. We will continue our investigations into this exciting area.

2. Below-Elbow

Below-Elbow Prosthetic System

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The objective of this project is to develop a below-elbow prosthetic system with hook/hand interchangeability and easily removable modular components. The components consist of a terminal device, battery, electronics package, electrode assembly, and wrist connector.

Design work has been completed with the exception of a holder for the battery and electronics. Prosthetics lamination techniques have been developed to mount the removable electrodes into a below-elbow prosthesis.

A manufacturer is in the process of preparing this system for production. This laboratory will work with the manufacturer in an advisory capacity.

[See also **V. Functional Assessment**, Quantification of the Functional Capacity of Upper Limb Amputees]

II. Orthotics

A. Lower Limb

Design and Evaluation of a Knee Orthosis

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Sponsor: Northwestern University
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The primary objective of this project is to improve orthotic treatment in the rehabilitation of the knee joint. Many knee orthosis designs do not achieve their intended goal because of mechanical or kinematic mismatches, which lead to motion restriction or binding, misalignment of the orthosis on the limb, and discomfort due to skin pressure problems. In response to the above situation, this laboratory has designed and developed an improved orthotic knee joint and complete knee orthosis. It was intended that this orthosis system be applied to total joint replacement cases, as well as other ligament-related problems of the knee joint.

The improved orthotic joints are semi-constrained and anatomically shaped, and were shown to have minimized the pistoning constraint normally associated with orthotic joints. Stability is added to the joints by the sequential tightening of a set of inextensible Dacron straps crossing the joint, simulating the knee ligaments. Anterior cruciate, posterior cruciate, and collateral ligament strap configurations were designed. Since the orthotic joints minimize the pistoning constraint, significant improvements to the orthotic interface could be realized, increasing its suspension to the lower limb. Interface improvements, based on a four-point suspension principle, include the use of a medial femoral suspension pad and a proximal tibial suspension member, each with its associated strapping arrangement.

At the beginning of this reporting period, the designs of the orthotic joints and the complete orthosis were finalized. The search for a competent and reputable manufacturer/orthotics laboratory was completed. The orthotic system was scheduled to be available to the public at large in mid-1984.

In the last reporting period, our biomechanics unit established a formal, ongoing Knee Rehabilitation Clinic, in collaboration with the Rehabilitation Institute of Chicago. Through this clinic, an evaluative clinical series has been ongoing during the present reporting period for the purpose of making design refinements to the orthosis system. The clinic team has worked with Northwestern's Center for Health Services and Policy Research to develop an improved methodology for the clinical evaluation of people receiving the orthosis, as well as other knee rehabilitation procedures. The knee clinic and evaluation will continue during the coming reporting period, but will be refocused to follow and evaluate selected people receiving the finalized orthosis design, using the improved clinical evaluative methodology mentioned above.

A laboratory evaluation method for knee orthoses was in the process of being developed during this reporting period. The technique was an instrumented spatial linkage and microprocessor to measure knee motion before and after application of an orthosis and to directly determine whether the orthosis is actually performing as it should.

During this reporting period the electrogoniometer, a calibration procedure, and the associated computer software have been constructed or developed. Actual evaluations will be performed during the upcoming reporting period.■

An Investigation into the Mobility of the Cerebral Palsied Child

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Sponsor: Scottish Home and Health Department

The principal activity of this research program is the investigation of the influence of polypropylene ankle-foot orthoses (AFO) on the gait of cerebral palsied children. The ultimate objective is the production of guidelines for the prescription, production, and use of the AFOs with cerebral palsied children suitable for routine clinical purposes. In addition to this main activity, a limited number of prototype wheeled mobility aids have been evaluated clinically for more severely involved cerebral palsied children.

Gait analysis is being conducted using the TV-computer gait analysis system installed in the biomechanics laboratory. Information is being obtained on the nature of the external moments in the sagittal plane at the hip, knee, and ankle generated by the ground-to-foot force vector. The influences on these

moments of the characteristics of AFOs and associated footwear adaptations are being measured. Load transducers and EMG are being used to monitor the interface conditions between the AFO and ankle-foot complex in the laboratory setting, and also over a longer period of time in other environments.

Initial investigations have been conducted on eight cerebral palsied and six normal children resulting in over 200 test runs. Further measurements are being obtained from additional children.

Analysis of the initial data has been completed. This has indicated that significant alterations to the ground-to-foot force vector and the external moments generated at the joints result from the use of the AFOs. In addition, significant changes may also result from very small alterations in the characteristics of the associated footwear, such as their wedge and rocker properties.■

Technical and Clinical Evaluation of the Self-Fitting Modular Orthosis

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Research activity on the Self-Fitting Modular Orthosis (SFMO), described in this report, is taking place at the Faculty of Electrical Engineering, Belgrade, and at the Rehabilitation Institute "Dr. Miroslav Zotovic," Belgrade.

The Self-Fitting Modular Orthosis is an assistive device for lower limb functional impairments. It is an adaptive, modular, lightweight external skeleton with soft interface. The goal of this project is to introduce this particular assistive device to general use in rehabilitation. Some of the properties of the SFMO which have already been verified are: self adaptivity to the body parameters, self adjustment to the human joints, soft interface providing favorable pressure distribution when external power is applied, orthosis portability, simple maintenance, and modularity.

Perhaps most important, however, is the possibility of integrating the SFMO with functional electrical stimulation (FES), thereby creating a hybrid orthosis (HO). The term hybrid orthosis is used here in the sense of a device which organizes parallel effects of FES, SFMO, and any existing (impaired) human neuromuscular function which may be potentially useful in locomotion.

Such "organized parallel action" can be expected only when full compatability of the artificial and natural systems exists in terms of energy, force transmission, and control. Achieving what we have just described is the central point of this project for evaluating control strategy with the man/machine system.

The model of the hybrid orthosis and the preliminary testings of the device, are based on the use of SFMO with cybernetic actuator, FES techniques developed at the Rehabilitation Engineering Center at Ljubljana, and nonnumerical control applying aspects of artificial intelligence. Recent experience suggests many advantages possible with successful application of hybrid orthosis: (i) the possibility of using available metabolic energy for functional movements; (ii) low external energy consumption; (iii) full application of available capabilities of the handicapped individual; (iv) increased patient safety; (v) reduction of fatigue during stance phase of gait; (vi) extended locomotion endurance; (vii) the use of hands in gait limited to a role in maintenance of balance instead of use to apply energy in gait; and, (viii) the "openness" of the biomechanical system possible with a hybrid system of the type modeled.

Prescription indications for hybrid orthosis include lesions and disorders of the central and peripheral nervous systems, including myopathies that have compromised severely the function of locomotion.

Preliminary studies with patients show that hybrid orthosis can be realized and that its possibilities are far greater than those of the individual components. One of the most important advantages of this approach is seen as the hardware and software "openness" of the system.

Further research activities are mainly directed toward a strategy of stimulation in order to achieve reliable bipedal locomotion with no hand support, cybernetic actuator development for orthotic purposes, software development based on artificial reflex arcs, and new special SFMO component development and evaluation.■

A Motion-Guiding Load-Bearing External Frame for the Knee

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The objective is to design an external linkage that reproduces normal knee motion, which can be incorporated into knee braces and external hinge-distractors. It is believed that accurate motion will avoid excessive surface contact forces, and will guide the ligaments into correct length patterns.

A study of the motion of the normal knee was completed in the first year of the project. Internal-external rotation, varus-valgus, a-p translation, and vertical translation were described mathematically in terms of flexion angle. The data were used as input in computer programs to generate the geometrics of external linkages which would reproduce this normal motion. The first linkage was a cam in a housing in conjuction with a pin in a slot, while the second linkage was a series of pins guided by slots. Conventional machining methods were used to produce prototypes of these designs, but the complex curvatures made accuracy difficult to achieve. Recently, N.C. machining has been used to produce accurate and reproducible parts. The important feature of the linkages is that the lateral and medial motions are different. On the lateral side there is considerable posterior translation of the femur with respect to the tibia with flexion, while on the medial side there is a smaller forward translation. The result is a net posterior translation of the femur on the tibia with flexion together with an internal rotation. This motion is considered to be important in its compatibility with the internal surface geometry of the knee, and in reproducing correct ligament length patterns.

The linkages, whether used in a brace or in a hinge-distractor, must be as small as possible, while having adequate wear resistance and strength. To test the wear, a 10-channel machine was constructed, which provided oscillatory motion under a constant load. Wear depth was regularly monitored using micrometer gauges. The geometry of the specimens was a metal rod located transversely on the edge of a plastic sheet, reproducing and rolling over the plastic surface. A variety of potentially viable materials were tested, including homopolymers, copolymers, and powder of fiber reinforced polymers. In all cases, the rate of wear under sliding conditions far exceeded that under rolling, some materials surviving only a few thousand cycles for 2 mm of wear. This was due to the combination of increased internal stresses and temperature buildup caused by the friction. The most successful materials to date have been Torlon™ and Delrin™, both of which are being tested further. Ultra-high molecular-weight polyethylene, used in total joint replacement, had too low a yield strength under the high contact stress conditions of our test.

The prototype linkages, using Delrin™, were incorporated into a leg brace. The importance of the cuff design and the accurate location of the linkages on the knee were recognized. The cuff design depends upon the application, whether prophylaxis in sports, post-injury or post-surgery, or for chronic instability. However, certain common principles such as correct overall geometry, location on bony landmarks, adequate surface area, cuff-to-skin friction, and adjustability must be accounted for. The prototype demonstrated good comfort, accurate motion, and lack of cuff slip in subjective testing to date. Instrumented linkages were constructed to obtain objective data. Strain gauges were applied to the upright bars which connect linkages to the tibial cuff to determine the forces and moments acting at the hinge location during activities. An electronic system consisting of bridge circuits, a-d converter, and microcomputer was assembled. Our anatomical motion design will be compared with fixed hinges and polycentric hinges with uniform lateral and medial motions. It is hoped to demonstrate the advantages or otherwise of reproducing more anatomical motion.■

[See also **IV. Spinal Cord Injury, B. Medical Treatment**, Longitudinal Assessment of Physical Therapy Factors that Affect Quality of Life of Persons with Spinal Cord Injury]

B. Upper Limb

Assessment of Hand Function and the Development of Wrist-Hand Orthoses

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Sponsor: Tayside Health Board

The Tayside Rehabilitation Engineering Services is responsible for the delivery of hand orthoses to a population of 180,000. Interest in improving existing knowledge of prescription criteria for hand orthoses,

as well as methods of fabrication and fitting, led to the initiation of this project.

A series of instruments have been developed that can be used in clinical practice to objectively assess hand function. The equipment consists of pinch, grasp, and skin shear transducers (the latter to assess recovery of skin sweating). The equipment is being used both to assess the immediate improvements in hand function that may be achieved by the application of orthoses, and to assess hand function recovery with time. Work is currently progressing in the development of software to permit the transducers to be interfaced to a microcomputer to produce graphical presentations suitable for use by the clinic team.

The same research team also is working on the development of modular hand orthoses, typically for application following traumatic injury. The correct timing of orthotic fitting in these cases is extremely important for the patient rehabilitation program, and the development of a modular system that can be assembled quickly is therefore highly attractive. A torque transducer has been fabricated to measure finger joint stiffness characteristics, and to compare these with the characteristics of orthoses. Commercial orthoses, as well as those developed in our own workshops, have been tested and their characteristics compared with the required characteristics derived from patient measurements.

Sensory Substitution System for Grasp Force and Hand Position Feedback

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A sensory feedback system is being developed to provide conscious information about grasp force and extent of hand opening in quadriplegic individuals who use FNS (functional nerve stimulation) orthoses to achieve grasp. Electrical stimulation of the user's skin in the region of the upper arm or upper back is being used as the basis for inputting the sensory information. The coding scheme being developed uses frequency modulation to signal the level of grasp force and uses the spatial position of the stimulation to signal the spatial extent of hand opening.

A study of stimulus parameters for the frequency modulation aspect of the coding scheme has revealed that using bursts of pulses, in which the number of pulses in each burst is made to vary according to the burst-repetition rate presented, affords a more easily discriminated code. With that scheme, subjects can distinguish six different frequencies in the range of 2.0 Hz to 55 Hz with at least 90 percent accuracy.

An innovation of the electrocutaneous system being developed in this laboratory is the use of chronic indwelling electrodes that stimulate the skin subdermally. This technique provides sensations that are more distinct, more consistent, and more comfortable than can be obtained with more conventional surface stimulation.

It is our ultimate intention to drive these indwelling electrodes via an implantable stimulator to diminish the amount of externally worn hardware needed for the system.

Present efforts are concerned with the design of an implantable-array electrode which will afford access to several adjacent regions of skin for implementation of the spatial position aspect of the feedback system. The work includes an investigation to specify the optimum number of electrode sites to employ in order to maximize the rate of information transfer.

[See also **I. Amputations and Limb Prostheses, C. Upper Limb, 1. General**, Myoelectric Controls for Orthotic/Prosthetic Systems]

III. Total Joint Replacement and other Orthopaedic Implants

A. General

Evaluation and Development of Biomaterials Used in Total Joint Replacement

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Sponsor: Northwestern University
Rehabilitation Engineering Program

At a recent meeting, an announcement was made that by centrifuging acrylic bone cement inherent porosity was removed and the mechanical properties were significantly increased. For several years, efforts have also been directed in these laboratories toward the removal of porosity to improve physical properties. However, medium vacuum has been employed, since it was felt that such an apparatus could be introduced to the surgical suite much more readily than a centrifuge. Moreover, preliminary results indicate that vacuum may have the additional advantages of removing more of the micropores, removing excess monomer that might have been transferred to the patient, and preventing the monomer vapor from reaching the clinical personnel.

Prototype vacuum mixers have been fabricated and are ready for simulated clinical trials. The necessary vacuum pumps have been purchased (the so-called suction vacuum, available in the surgical suites, is far too weak to be effective in the current mixing system). The decrease in porosity via vacuum mixing presently appears to work best in the more fluid cement mixtures. While porosity appears to have been removed in large boluses of dough-type cements, bubbles and holes seem to reappear in small ASTM F451 specimens. Studies are currently underway to see if the nature of the multiple-hole specimen dyes and plates inherently introduce defects to setting acrylic bone cement specimens.

Also under scrutiny during the reporting period are the evaluations of corrosion resistance of various porous metal prosthesis components. The methodology being employed is that of anodic polarization in body-simulated electrolytes, following procedures similar to those being developed in these laboratories and with others for ASTM F746 Standard on Pitting and Crevice Corrosion in Surgical Implant Metals.

Preliminary results are showing corrosion electrical currents of porous coatings to be at least one order of magnitude greater than that of bulk material of the same composition. This is probably due to the significant increase in surface area presented by a porous material. However, during our corrosion evaluations, several coatings were found to strip easily from their parent prosthesis. This, and the findings of others, has caused several models to be temporarily withdrawn from the market until more suitable sintering techniques can be discovered. In the meantime, with a temporary hiatus in the supply of freshly coated porous prostheses, further pursuit in performing all potentiostatic testing via Apple personal computers equipped with appropriate A/D boards is ongoing.

Investigation of the Bone/Bone Cement/Implant Interface Formed by Total Joint Replacement

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Sponsor: Northwestern University
Rehabilitation Engineering Program

The objective of this project was to identify the causes of late loosening of total joint replacement components by examining three aspects of the interface system:

1. Investigations of the major factors affecting the mechanics of bone/bone cement interface failure. A series of control and experimental tensile tests on the bone/bone cement interface had been reported previously. A paper detailing results of these tests has been accepted for publication by the Journal of Orthopaedic Research.

2. Investigation of mechanical and histological properties of the soft interface tissue commonly found at the bone/cement interface system and how load is transferred across this interface. A paper presenting the permeability results and soft-tissue mathematical model reported last year has been accepted for publication in the Annals of Biomedical Engineering.

Also, the tissue response to unloaded cylindrical titanium implants in rabbit tibiae was investigated as

a precursor to future experiments. The response was seen to be no different from ordinary fracture healing, with a bony shell surrounding the metal and no fibrous liner observed.

3. The development of an evaluation methodology based on fracture mechanics, for bone cement/metal implant interface failure, and its utilization to evaluate various metal surface preparations. Titanium bar stock has been machined to four-point bent bar dimensions and the bar's surfaces either grit-blasted (which is the normal implant's surface state) or flame-sprayed (which is a porous surface state). These specimens await testing, and therefore no data is available.

Structural Analysis of Total Joint Replacement

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Sponsor: Northwestern University
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The finite element method was used for the structural design and analysis of total joint replacements and was specifically used to address the following two subproject areas:

Surface Replacement Hip Arthroplasty—The surface replacement hip arthroplasty is a promising procedure for the younger, more active population. The objective of this project is to better understand the causes of surface hip arthroplasty failures and to develop improved designs. Finite element analysis is being used to calculate the three-dimensional stresses in the remaining portion of the head and neck of the femur after physiological loads are applied to the prosthesis. The purpose of this analysis is to find a design for the surface hip replacement that will minimize changes in stress distributions from the preoperative hip. It is hypothesized that, by maintaining the same stress distribution, the mechanically induced resorption of bone will be minimized. Several designs have been analyzed and more remain under consideration. These studies have been done using a typical human femur as their basis. A parallel study also is being conducted, using dogs for the basis of analysis as well as for corroborating experiments. These experiments will be used to test the hypothesis and, hence, put confidence levels on the validity of this approach for prosthesis design.

Finite Element Analysis of the Proximal Femur and Femoral Component of a Total Hip Replacement—The objective of this project is to determine the consequence of the fibrous tissue layer on the stress distribution of the total hip implant system. A realistic element that models the fluid-filled interface tissue has not been developed to date. In the past, two extreme (three-dimensional) finite element cases have been run, modeling a hip with a perfect interface bond (a porous implant with 100 percent ingrowth) and one where there was no interface bonding on the distal half of the stem. It is presumed that these two cases represent the more typical behavior. To perform a more realistic model of this fluid-filled fibrous interface material, a project has been undertaken to develop an element that considers biphasic (that is, fluid and solid) material properties. The current effort on this project is implementing and validating this element so that better biomechanical models can be implemented in the future.

Development of a Biologic Cement for Fixation of Skeletal Implants

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Sponsor: National Institute of Handicapped Research

Implants with porous surfaces intended to allow ingrowth by bone have been developed as a way to avoid the problems of loosening that have been encountered when implants are held in place by acrylic cement. A disadvantage of the "porous" implants as used presently is the large inventory required to have the correct size available. To alleviate this problem, a fixation medium is needed that can be replaced by new bone as the fixation material is resorbed gradually. To achieve this, experiments are being carried out on dogs using various filler materials, such as decalcified bone paste, autogenous ground bone paste, and tricalcium phosphate crystals.

Results to date are very encouraging.

Late Loosening in Total Joint Replacement in the Lower Extremities

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Summary—A biplane radiography technique was developed to measure the motion at the cement-bone interface of patients who had either a total knee replacement or a total hip replacement. Spherical cobalt-chromium markers were embedded in the cement and in cortical bone. The relative position of the balls was measured radiographically postoperatively and at 6 months intervals thereafter. The resolution of the measurement was 0.2 mm. Of the 68 patients who volunteered for this program, 54 patients were suitable for the study. Reversible displacement (relative motion during a change from weight bearing to non-weight bearing) and migration (relative motion over time from one non-bearing study to another) were calculated. The range for symptomatic reversible displacement was 0.4 to 4.5 mm, while that for asymptomatic reversible displacement was 0.3 to 1.9 mm. All reversible displacement of less than 0.4 mm was asymptomatic. Migration of as much as 2.1 mm occurred without concomitant reversible displacement. All radiolucent lines correlated with measured reversible displacement. Half of the patients who were evaluated 2 weeks postoperatively had measurable reversible displacement.

Conclusions—(i) Biplane radiography is a useful clinical technique; (ii) The incidence of measured reversible displacement (75 percent) is higher than the incidence of clinical loosening (9.6 percent in this series)■

Diagnosis of Loose or Damaged Total Joint Replacement

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

It has been demonstrated that information gathered from acoustic emission monitoring of total joint replacements can contribute to the other clinical findings in diagnosing mechanical degradation. During the next year of support, the technique of correlation plots to examine the acoustic emission waveform characteristics will be applied to data from the increasing population of total joint patients monitored at the Hospital for Special Surgery. The objectives will be to further identify the most significant characteristics (in terms of correlation with clinical findings) and to describe the in vivo acoustic emission data in a manner that could allow separation between signals from different damage mechanisms.

The first objective is aimed at optimizing the clinical application of the acoustic emission equipment. The second objective will examine whether or not acoustic emission monitoring can be used to identify not only the presence of mechanical degradation but the source of the degradation as well. This source identification requires information on acoustic emission from the mechanisms contributing to the degradation. A third objective will be, therefore, to begin to examine static and cyclic failure in cancellous bone and in the bone-cement interface and to continue to examine damage at the prosthesis-cement interface. Specimen geometries for the biomaterial bone-cement and prosthesis-cement tests will first be modeled with further finite element studies to verify failure locations and to establish test configurations in which the same specimens can be used to produce more than one type of damage mechanism■

Cementless Hip and Knee Prostheses

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Sponsor: National Institutes of Health
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The long-term results of conventional cemented total hip replacement show a deterioration with time, such that beyond 10 to 15 years the failure rate may rise to as high as 40 percent. In younger, more active patients, a failure rate of 50 percent at only 5 years has been reported. Revision surgery is difficult and most often leads to a result which, radiographically at least, will be much shorter lived than the primary case. Sometimes revision surgery involves serious bone loss, jeopardizing the future viability of the entire reconstruction. Neither surface replacement nor bone ingrowth is seen as the answer.

However, there now has been 30 years of clinical experience with noncemented femoral components, such as the Austin-Moore. While the failure rates are

not lower than with cemented stems, a large proportion of the failures are associated with acetabular protrusion, while in many other failures a poor fit of the stem in the canal is implicated. The loss of bone associated with failure and removal is generally much less than with cemented stems.

It is proposed that a stem designed to be a close fit in specific load-bearing areas, a "close-fit stem," may well provide the answer to reliably obtaining a durable result. Our aims are to determine the required sizes and shapes of such a stem to test the fit and the load transfer in vitro and the biological response in vivo. Color computer graphics will be used to model the shape and size ranges of the femoral canal, while a stem fit program will determine the number of stems required to specified accuracies. Closeness of fit will be tested on actual bones using sectioning techniques. Bone strains and stem-bone shear movements will be compared for cemented stems, the Austin-Moore, a metallic close-fit stem, and close-fit stems with a polymeric coating.

These designs will be tested in a bovine model to observe the differences in bone response and to test whether the bone appears to adapt more satisfactorily to the close-fit stems. For possible augmentation of closeness of fit and encasement of a close-fit stem with new load-bearing bone, osteogenic stimulating demineralized bone powder (DBP) will be used as a filler. This work will provide valuable data of the viability of a close-fit stem. If such a scheme is successful, it will have an invaluable place in hip surgery■

Mechanisms of Orthopaedic Implant Loosening

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Sponsor: National Institutes of Health
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Orthopaedic joint reconstruction with an implanted artificial prosthesis is an increasingly common surgical procedure. Unfortunately, at least 7 percent of patients receiving such prostheses will experience implant loosening and, ultimately, failure within 5 to 7 years of surgery.

The precise reasons for this high rate of failure are unknown. However, histological studies of the tissues surrounding loosened implants suggest that mononuclear phagocytes (MOs) and foreign body giant cells (GCs) play an important role in the rejection process. Specifically, these cells, which seem to be recruited by implant-derived particles, are believed to be directly responsible for resorbing the bone immediately surrounding the implant and are perhaps instrumental in the development of an inappropriately thick connective tissue capsule between the implant and the supporting tissue.

However tenable the hypothesis regarding the role of MOs and GCs in implant loosening, it is based upon histological observations and is therefore, at best, intuitive. The aim of the present proposal is to directly assess the potential of MOs and GCs to affect those changes believed essential to the prosthetic loosening, particularly when exposed to implant-derived materials. These studies will focus on use of in vitro assay systems, established in this laboratory, with which we have previously (i) documented the ability of MOs to resorb vital and devitalized bone, (ii) demonstrated that bone matrix degradation can be precisely quantitated, and (iii) shown that MO- and GC-mediated bone resorption can be regulated by systemic bone-seeking agents (e.g., cortisol) and by, as yet, undefined factors released by other cells. In this application, we propose to extend the use of these techniques and experience to: (i) evaluate the action of implant materials on MO- and GC-mediated bone; (ii) identify the enzyme(s) responsible for bone collagen degradation by MO and GC and explore the regulation of this enzyme(s) by implant materials; (iii) study the potential of MOs, GCs, and endothelial cells exposed to implant-derived material to modulate (stimulate) bone resorption by other cells, including osteoclasts; and (iv) establish whether phagocytosis of implant particles by MOs promotes the release of agents capable of stimulating giant cell formation and fibroblast proliferation■

The Mechanical Properties of Porous-Coated Orthopaedic Alloy

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Introduction — The development of porous-coated orthopaedic implant devices for attachment by bone ingrowth has been the subject of much research. A porous metal coating applied to a solid substance has been shown, in vivo, to offer advantages over current methods of fixation. These include a higher interface shear strength between implant and bone and a more

uniform distribution of stresses. These devices, however, require a sintering heat treatment to apply the porous coating. Sintering heat treatments have been shown to have a detrimental effect on the material mechanical properties of some orthopaedic alloys.

One of the materials of choice for porous-coated systems is Ti-6A1-4V alloy. This is based upon its high corrosion resistance, low toxicity, and favorable mechanical properties. However, the fatigue strength, the most important mechanical property when considering the design of a load-bearing orthopaedic device, has been found to decrease due to both the sintering heat treatment and the porous coating.

In our previous studies, uncoated Ti-6A1-4V orthopaedic alloy was found to have an endurance limit of 605 MN/mV. The application of a porous Ti-6A1-4V coating decreased the endurance limit of the system by approximately 77 percent, and when the uncoated substrate material was only heat treated to the same temperature as the porous-coated samples (125°C for 2 hours), a degradation of approximately 34 percent in fatigue strength was observed. The great difference between the porous-coated samples and the only heat-treated samples was theorized to be due to the porous coating acting as a notch, since the introduction of a machined notch was found to decrease the endurance limit of the material by 65 percent.

The reduction of fatigue properties by the heat treatment is due to the transition from the as-received equiaxed microstructure to the lamellar structure upon sintering. This lamellar structure has been shown to have inferior fatigue properties relative to the equiaxed structure. Thus, the need for a heat treatment to improve the fatigue properties after sintering seems apparent.

Methods—In the present study, microstructural analysis was performed on six different post-sintering (1250°C for 2 hours) heat treatments of Ti-6A1-4V in an attempt to improve the fatigue properties. The heat treatments were:

1. Argon quench;
2. Argon quench, followed by a 4-hour anneal at a temperature low in the α and β region with a subsequent Argon quench;
3. Cool to just above β-transus, slowly cooled through β-transus, and furnace cooled;
4. Argon quench followed by a 15-minute anneal slightly above β-transus, slowly cooled through β-transus, and furnace cooled;
5. Argon quench preceding an anneal at just below β-transus for 4 hours followed by an Argon quench;
6. Argon quench, then anneal at slightly below β-transus, cooled very slowly to a temperature low in the α and β region, then Argon quenched.

Results—The six heat treatments produced alternative microstructures from the lamellar structure obtained in the sintering heat treatment where slow cooling from the sintering temperature took place. Quenching from sintering temperature (heat treatment 1) resulted in shorter, fine interwoven α plates with localized areas of equiaxed α and fewer colony boundaries. Annealling this structure in the low α and β region for 4 hours (heat treatment 2) produced a microstructure with large α plates of varying dimensions and orientation differing from a lamellar structure. Annealling at a temperature just below the β-transus (heat treatment 5) resulted in large α plates which became more globular and equiaxed, and the retained β more dispersed. The outside of the sample exhibited a 0.12 mm layer of an acicular α in a β or finely transformed β matrix with a few small globular α particles dispersed in the layer.

Slow cooling through the β-transus (heat treatments 3 and 4) produced a transient structure that showed some areas of an equiaxed structure. The differences between the two heat treatments were minimal, and thus the Agron quench before the β annealling and slow cooling through the β-transus makes little difference. The recrystallization annealling (heat treatment 6) resulted in a structure of coarse α plates in an abundant and very fine martensitic matrix. This structure was uniform throughout, free of any type of colony boundary.

Discussion—In previous studies, where the sintering heat treatment was followed by a slow furnace cool to room temperature, a lamellar structure consisting of large colonies of α plates in the same crystallographic orientation with β retained between them was obtained. It has been shown that crack propagation can occur easily in both parallel and perpendicular directions to the long axis of the alpha grains. The heat treatments described above provide microstructures somewhat different from the original sintering heat treatment, with some exhibiting considerably different microstructures. Thus, these heat treatments may help in resistance to crack initiation and propagation during the cyclic loading of porous Ti-6A1-4V orthopaedic devices, and thus result in improved fatigue properties. To date, limited fatigue testing has shown an improved endurance limit for some cases. However, more tests are being performed to determine statistical significance.

Biomechanics of Bone Resorption/ Regeneration at a Bone-Implant Interface

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Introduction—It is generally acknowledged that loosening of orthopaedic implants in bone is a leading cause of failure of joint replacements. However, while there have been suggestions that mechanical factors influence the response of bone at implant-tissue interfaces, and thereby relate to the loosening problem, little has been done to clarify the quantitative role of such variables as relative motion or stress concentrations at the interface. Therefore, this project has been aimed at elucidating relationships between bone remodeling and mechanics at a bone-implant interface.

Methods—The plan involves use of an animal model, together with engineering methods and quantitative histomorphometry to perform an in vivo experiment. The rationale is to create well characterized states of stress in the interfacial region of implants in bone using specially designed implants and loading protocols, then to utilize histomorphometry to assess remodeling activities in relation to the in vivo loading history. Both trabecular and cortical bone sites are being used. To create well defined mechanics at bone-implant interfaces, the implants are placed in bone using special atraumatic techniques and left undisturbed for 2 to 3 months to establish a direct, or very nearly direct, bone-implant contact interfacially. Subsequently, the implants are directly loaded with a controlled loading pattern for a fixed period of time. The interfacial mechanics related to the controlled loading are predicted using finite element analysis (FEA). The histomorphometry includes analyses of fluorescent labeling plus osteoblastic and osteoclastic activity in tissue sections taken from each region of the interface that has been quantified as to mechanical history. The experiments employ beagle dogs (mandibular trabecular bone and radial cortical bone) and special implants of a screw shape made of implant-grade pure titanium.

Preliminary Findings—As part of the engineering phase of the project, finite element analyses have been made of relevant implant-bone problems. In these analyses, the initial goals have been to investigate the stress fields around certain implant shapes and to document the importance of the assumptions about contact at the bone-implant interface. Three implant problems were simulated: (i) bone screws in cortical bone, (ii) coronal sections through a dog mandible containing an inverted T-shaped implant, and (iii) sagittal sections through the same type of implant. Each problem was run for infinite friction (bonding) and no friction (nonbonding) interfacial assumptions using isoparametric elements with quadratic shape functions. Frictionless contact was introduced via an algorithm based on Lagrange multipliers.

Results—For the same stress analysis problem, the interfacial stresses are very different for the bonding versus nonbonding assumptions. Not only are the stresses quantitatively changed, but also they show important qualitative differences. For example, in the case of an axially loaded mandibular implant that resembles an inverted T-shaped beam embedded in bone, the bonded case shows maximum compressive principal stresses near the neck and ends of the implant, while the nonbonded case shows these same interfacial regions to experience maximal tensile principal stresses. Also, for both the dental implant and bone screw analyses, those models with nonbonded interfaces show regions where actual gaps develop between bone and implant, while in the bonded cases, such gaps do not appear because of the tensile stresses that can develop across a bone-implant interface in the bonded case.

Discussion and Future Plans—From these initial studies, it is clear that the predictions of FE models of implants in bone are dependent on whether or not bonding (i.e., infinite interface friction) exists at bone-implant interfaces. This fact must be considered when evaluating the fidelity with which an FE model represents a particular bone-implant situation. Hence, we have been able to design the implant experiment with more confidence in our ability to model the actual conditions that may arise at bone-implant interfaces. With the initial engineering analyses in hand, the next step is to conduct the in vivo study. A loading apparatus for the implants is being designed, and the implant locations and actual loading protocols are being tested. The in vivo loading will be applied to the implants under microcomputer control for half an hour per day for 5 days, with a 0.5 Hz cyclic pattern involving loads of magnitudes sufficient to create meaningful stress fields in interfacial bone, as judged from our initial finite element studies■

Evaluation of Total Joint Loosening Using X-Ray Photogrammetry

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Loosening of the prosthetic components continues to be the largest problem with total joint replacement surgery. Our research project has developed a method which can accurately measure the distance that a prosthetic component settles after it has been placed in the bone, or the amount of loosening that has occurred with use. Our efforts this year have focused on developing the equipment to perform X-ray photogrammetry measurements in a clinical setting, and on convincing the companies that manufacture prosthetic components to add markers that will show on X-ray films.

Methods—X-ray photogrammetry is the process of accurately determining the three-dimensional coordinates of marker points in the bone and on the prosthetic components from two radiographs taken simultaneously. By using 1 millimeter-diameter stainless steel spheres in the bone and marker points on the prosthetic components, an accuracy of 0.1 mm can be achieved in determining the spatial locations and movements of the bones and total joint components. The equipment necessary to achieve this accuracy consists of a calibration frame that puts reference marks on the X-ray films, a high-accuracy digitizer to determine the coordinates of the marks on the film with an accuracy of ▲10 μm, and a computer program to transform the two-dimensional coordinate data from two films into three-dimensional coordinates.

Progress—Since the digitizers currently available do not have the necessary accuracy (the standard is a resolution of ▲μm and accuracy of ▲125 μm), we have developed a digitizer, using optical linear encoders for the x- and y-axes, which has a resolution of 1μm and accuracy of ▲10 μm. The digital output from the encoders is translated into x- and y-coordinates and transmitted to the computer program for storage with the reference number of the marker. The system has been tested and found accurate for measuring motions in three dimensions as small as 0.1 mm.

Our current efforts consist of measuring patients, who have had total joint replacement surgery, with markers placed in their bones around the prosthetic components to track the subsidence of the components over a period of time, or loosening of the components with use. Our other effort consists of attempting to find a manufacturer who can produce the hardware for the X-ray photogrammetry system so that it can be made available for use in a clinical trial. This also involves convincing the implant manufacturers to add the markers to their prosthetic joint components■

Bacterial Colonization of Surgical Biomaterials

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Significant progress has been made to demonstrate that biomaterials act as a substrate for microbial adherence and colonization and that the process is a fundamental cause of sepsis in biomaterial-related surgery. As a corollary objective, our studies also show preliminary evidence that diseased or compromised tissue (i.e., bone-joint synovium, diseased tissue, etc.) also serves as similar nidi or substrate for colonization and the septic process (i.e., primary or secondary osteomyelitis, septic arthritis, post-nonbiomaterial surgical sepsis).

In the forthcoming year, work will continue in Aim #1, "To isolate pathogenic bacteria from infected biomaterials," with the inclusion of nonorthopaedic biomaterials. Our initial studies show that biofilm formation is a general phenomenon in the colonization of inert surfaces of cardiac pacemakers, urinary catheters, intrauterine contraceptive devices, vascular catheters, and vascular grafts, and that this mode of growth confers on these pathogens resistance to host defense mechanisms and antibacterial agents. We have expanded our original sampling to include, in the absence of biomaterials, diseased and compromised tissue (i.e., dead or damaged bone, joint synovium, etc.).

Aim #2, "To maintain isolated pathogens in an adherent form," and Aim #5, "Behavior of macrophages towards biomaterials," have been achieved during the past 2 years. Aim #3, "Chemical characterization of the exopolysaccharides of pathogenic isolates," will be completed without modification. Special attention will be focused on Aim #4, in which the

proposed study of the kinetics of biomaterials development also will assess the inherent antibiotic resistance of cells in mature biofilms.

In summary, we can say that Aims #2 and #5 have been achieved, that work continues in Aim #4 by means of an expanded and improved methodology, and that Aims #1, #3, and #6 will be completed■

In Vitro and In Vivo Corrosion of Orthopaedic Implants

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The long-term use of metallic orthopaedic implants is associated with a small but finite risk of adverse biologic reactions to metal ions released as corrosion products. The proposed continuation of this research program is designed to: improve our understanding of the mechanisms of and methods for measuring corrosion and the biologic distribution of and reactions to corrosion products; to explore methods for reducing corrosion rates and diagnosing conditions indicative of excessive corrosion; and, to investigate reactions to corrosion products.

Laboratory corrosion-rate measurement experiments utilizing electrochemical techniques will be continued to examine in more detail the interactions between static and fretting corrosion of stainless steel, cobalt alloy, and titanium and specific proteins at pH values associated with inflammation and wound healing. Laboratory and animal studies with sheep will continue to examine the role of fracture stability and screw tightness on the amount of and temporal changes in fretting corrosion of osteosynthesis plates and screws.

Metabolic studies with hamsters injected with metal salts or corrosion products will be continued. These studies will focus on the question of whether metal ions remain at the site of release, whether they are transported in the blood to other sites where they could cause an adverse reaction, or whether they are excreted in the feces or urine. Similarly, these studies will determine if the distribution of metal salts is different when the metal salts are given a second time. Answers to these questions will improve our understanding of location of potential biologic reactions associated with corrosion, as well as determine the validity of chemical analysis of excretions for assessment of in vivo corrosion rates.

Biomechanical and histological studies with rabbits injected with metal salts or corrosion products, in which metal screws are then implanted and tibial fractures are stabilized with intramedullary rods, will be continued to determine the functional significance of reactions associated with corrosion and metal allergy. These studies also will examine the question of whether the incidence and nature of biologic reactions are related to the type of metal used for internal fixation of fractures, and whether an animal with an allergy to one metal can be treated with an implant alloy not containing that particular element■

Intermediate Organometallic Corrosion Products

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Sponsor: National Institutes of Health
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Metallic implants are used in large numbers in the practice of orthopaedic surgery. All metals in use have finite corrosion rates. A variety of clinical problems have been proposed involving metabolic, immunologic, bacteriologic, and carcinogenic responses associated with release of metal by corrosion or other reactions. Research to elucidate the possible connections has been hampered by a lack of knowledge of the molecular form that the corrosion products take and the concentrations in which they are present in patients. In particular, it has been proposed that a variety of biologically active organometallic intermediate compounds exist as a result of corrosion in vivo.

The object of this proposed research project is to detect, isolate, quantitate, and partially identify the blood-borne organometallic compounds that arise from the corrosion of the two most common orthopaedic metallic alloy systems: stainless steel and cobalt-chromium.

The studies proposed involve HPLC fractionation of serum and treated tissue fragments followed by atomic absorption spectroscopy. The studies use a small animal/microsphere implant model to examine the effects of implant area/animal body weight ratio on the production of organometallic complexes and to predict the possible findings in patients■

Study of Wear Particle Analysis in Human Artificial Joints

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During the past year investigations have continued into the ferrographic analysis of the wear particles of human joints and their pathophysiological implications. A series of synovial fluids taken from end-stage osteoarthritic knee joints at the time of surgery for total joint replacement have been examined by ferrography. These samples provided unexpectedly few particles, possibly because of the restricted use of the joints prior to surgery. Histological examination of the synovia confirmed the ferrographic analysis.

Following our demonstration that wear particles could elicit the production and secretion of chondrolytic enzymes by cultured synovial cells, we have recently shown that particles of lapine articular cartilage produce an experimental arthritis when injected into the knees of rabbits. We are now attempting to identify the components of cartilaginous particles that produce these effects. In preliminary work, we have found that purified cartilage proteoglycans activate cultured synovial cells and produce an inflammatory response when injected into rabbits' knees.

Retrieval and Analysis of Orthopaedic Implants

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As part of our ongoing implant retrieval and analysis program, the correlation of tissue reaction to the degree of corrosion in retrieved stainless steel osteosynthetic devices was evaluated.

Methods—Clinical materials were obtained from 11 patients, of which seven were male and four were female, with a mean age of 28.8 years (range: 4 to 61 yrs.). These patients had 13 stainless steel (316L) internal fixation devices that were removed. Ten devices were inserted for acute trauma, two for hip fusion, and one for a fracture nonunion. Seven of the devices were removed routinely after fracture healing, while the remaining six devices were removed for symptomatic reasons. Of these removals, four plates were removed because of pain localized to the area of the implant after fracture healing was complete, one device was removed because of an infected nonunion of a hip fusion, and one plate was removed at 3 months because of a secondary fracture in the same extremity which required surgical treatment.

At removal surgery, a biopsy of the fibrous tissue strip overlaying the plate was taken. Bacterial cultures also were taken at this time. The strip of tissue and the plate were marked at the proximal ends with silk sutures for identification purposes. The tissue was then placed in a buffered formalin solution. Each screw was returned to its respective hole in the plate and was fixed in place with tape to enable a direct correlation of screw and plate corrosion. These 13 plates had 70 screw plate junctions with adequate corresponding soft tissue biopsy for histologic evaluation.

The soft tissue biopsies were embedded in paraffin, sectioned to a thickness of 6 μm, and stained with either hematoxylin and eosin, Gomoris Trichrome, Perl's Iron, or Bathophenanthroline Iron. The sections were then graded on a scale of 0 to 5 for degree of tissue reaction.

Upon receipt, the retrieved implant devices were thoroughly cleaned with a mild detergent and water. When necessary, a soft brush was used to remove adherent tissue and blood. Each screw-plate interface was then examined under a stereomicroscope and graded on a 0 to 5 point scale for degree of corrosion.

Three major components of the host-implant interaction were then examined using linear and nonlinear regression analyses. They were the relationship of corrosion to tissue reaction, the change in corrosion with time, and the change in tissue reaction with time.

Results—The mean scores and standard deviations of tissue reaction and corrosion were calculated. The means of the tissue reaction and corrosion scores for the entire study and for symptomatic and asymptomatic removals are given in Table 1. The normality of distribution was evaluated by the Kolmogorov-Smirnov Method. Linear and nonlinear regression analyses of corrosion score, tissue score, mean tissue score, mean corrosion score, and the ratio of tissue to corrosion score (T/C) were performed.

A good correlation of corrosion-to-tissue reaction was found that was improved by removing the symptomatic cases from the regression sample. Tissue reaction was directly proportional to the increased corrosion in the asymptomatic group. There was no correlation of symptomatic corrosion and tissue score. There was no correlation of corrosion with time; however, both asymptomatic tissue reaction and a symptomatic tissue reaction showed a good negative correlation over time. This indicated that a slight decrease in the tissue reaction occurred as the duration of implantation increased. The four patients having symptomatic removals for pain located in the area of the implant had complete pain relief following removal.

Discussion—What is the clinical significance of local tissue toxicity around stainless steel implants? Corrosion occurs only in the small area of the screw-plate interface, and even within this area the corrosion may be very localized. There was no correlation of the severity of corrosion with the duration of implantation. This implies that the major corrosion probably occurs during the period immediately after implantation and then remains at a constant level. Another finding that is of critical importance is that the amount of tissue reaction decreases with time.

Therefore, it appears that the body has an adequate method for removing toxic metals at a rate greater than the rate of release. Even in the plates removed for pain, there is a significant tendency toward decreasing tissue reaction at $p<0.025$. Correlating tissue reaction to corrosion suggested that there were two groups of patients in this study. The first group demonstrated a positive correlation of tissue score with corrosion. The second group's tissue score did not correlate with corrosion. This finding suggests an abnormality in the host's response to the implant.

One patient, a 31-year-old female with internal fixation of a radius with device removed at 18 months after surgery, was found to have moderately severe tissue reaction and lymphocytic perivascular infiltrates. Typically, a perivascular infiltrate is associated with allergic processes. The relation of tissue reaction and corrosion and the presence of a lymphocytic infiltrate suggest that some of the cases in this study may have a metal allergy.

On this basis of our findings, we do not recommend routine removal of stainless steel implants to prevent metal toxicity; however, in the case of a painful implant that is not associated with infection or nonunion, removal will probably relieve the pain. In the event removal is not possible, evaluation for metal allergy and replacing the implant with a nonallergenic implant may be beneficial■

TABLE 1
Tissue and Corrosion Scores Evaluated by Mean, Standard Deviation, and Kolmogorov-Smirnov (K-S) Testing

Tissue Score	Mean	Standard Deviation	Number	Normality Distribution
all devices	2.37	1.18	13 Plates (70 Holes)	$p<0.05$
asymptomatic removals	2.32	1.18	9 Plates (49 Holes)	$p<0.05$
symptomatic removals	2.48	1.17	4 Plates (21 Holes)	$p<0.05$
Corrosion Score				
all devices	1.87	1.63	13 Plates (70 Holes)	$p<0.05$
asymptomatic removals	2.06	1.65	9 Plates (49 Holes)	$p<0.05$
symptomatic removals	1.43	1.58	4 Plates (21 Holes)	$p<0.05$

Implant Fixation by Post-Insertion Pressurization of Polymethylmethacrylate

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Loosening and clinical failure of total joint prostheses is a multifactorial problem, but the single most common cause of loosening is failure of the bone cement interface. The purpose of this project is to develop a clinically feasible method by which acrylic bone cement can be injected into bone under pressure with maintenance of the pressure until polymerization is complete. Factors that relate to the incidence of loosening are cement porosity, the depth of penetration of the cement into bone, motion of the implant during polymerization, and the quality of the bone into which the cement is injected.

A total knee replacement for use in the canine has been developed, which incorporates the following features:

1. A single axis of motion, a design known to be associated with a high rate of loosening, to provide a worst case analysis of the data.

2. Short stems which do not reach the diaphysis of either the tibia or femur to avoid the known propensity of the canine femur to produce an excessive amount of periosteal new bone and cortical resorption after diaphyseal implantation.
3. Rigid fixation of the implant to bone before and during insertion of the cement.
4. Canulated stems through which the cement is injected.

A new hand-driven delivery system has been designed which is capable of generating and maintaining an injection pressure of up to 100 PSI.

Preliminary in vitro studies with human femora are underway in order to establish optimal pressure and cement-type for future canine application.

Acrylic bone cement, Zimmer LVC or Howmedica Simplex, is being injected into the proximal femur from paired fresh human cadavers under pressures of 20, 40, 60, and 80 PSI. The pressure is maintained with the hand-driven delivery system for 8 to 9 minutes with LVC and 12 to 14 minutes with Simplex.

The femora are cut into predetemined cross-sections for analysis as follows:

1. Porosity of the bone cement,
2. Shear strength of the cement,
3. Shear strength of the bone-cement interface,
4. Ash and calcium content of the bone,
5. Depth of cement penetration into bone.

At the present time, limited preliminary data are available on cement porosity and the shear strength of the bone-cement interface.

The specimens for porosity determination are spray painted, polished with silicon carbide sandpaper, and photographed. The slides obtained are projected at a magnification of 40X, and the pores digitized (Summagraphics 2000). The data are computerized to provide a porosity index (percentage of cement core occupied by pores), the average pore diameter, and number of pores counted.

Cross-sections for shear testing of the interface are further cut into 10 mm by 5 mm sections. The sections are mounted in a specially designed testing device and sheared to failure at the bone-cement interface in a MMED Matco hydraulic press at a constant head speed of 0.5 mm/sec.

Results

Porosity—At this point, with data on a very small number of specimens, the type of cement used seems to be more significant than the level of pressure applied. We could see no reduction in porosity between 20 and 80 PSI, whereas the number of pores was greater but the porosity index and average pore size were considerably less in LVC, as compared to Simplex.

Shear Strength—The initial data seem to indicate that the nature and quality of the bone are more significant than the pressure with which the cement is introduced. Statistical evaluation is not yet possible because of sample size, but it does appear that the shear strength and total energy absorbed increases more with LVC as compared to Simplex cement in response to pressure of injection.

[See also **VII. Wound and Fracture Healing**, Effect of Stress and Motion and Repair of Hard and Soft Tissues]

B. Hip

Biomechanical Assessment of Patients Treated by Joint Surgery

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Sponsor: Bioengineering Unit,
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Surgical replacement of lower limb joints has been practiced for 20 years, although there is little quantitative information on loads transmitted either by implants or by other related joints. The results of tests presented evaluate the variation in external forces developed between the ground and foot during walking, together with the configuration of the lower limbs and the moments acting about the hips and knees.

Two groups of patients were investigated: patients who were assessed prior to joint replacement and at intervals thereafter, and patients for whom the Girdlestone procedure was performed following a failed implant. The results are compared with those from similar tests on clinically normal subjects. There is a significant improvement postoperatively in the mechanical aspects of hip function for the replacement patients. The improvement continues after the first 6 months postoperatively and may result in abnormally high loading at other joints. At 12 months the performance of the patients with joint replacement differs significantly from the normal subjects, and is generally better than the Girdlestone patients.

Further modeling to determine muscle and resultant joint forces shows that in the joint replacement group, the hip, and particularly the medial compartment of the knee of the contralateral limb, may be subjected to significantly higher loads than those seen in either the operated limb or in the normals. This elevated loading may predispose these joints to the accelerated degeneration seen in patients with rheumatoid arthritis■

Quantitative Analysis of the Effect of Total Hip Arthroplasty on Stress and Strain in the Human Pelvis

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Two decades of experience with total hip arthroplasty have shown it to be one of the most successful procedures for treating the arthritic hip. While most patients achieve excellent results, a small percentage develop complications severe enough to cause failure of the arthroplasty. The most common cause of failure is loosening of either the femoral or acetabular component. Improvements in stem design and implantation techniques have increased the longevity of femoral components. With this increased longevity, failure of the acetabular components has become more prevalent. New acetabular cup designs and implantation techniques have been proposed to further improve the arthroplasty. However, there has been little objective experimental evaluation of the effects of these changes on the stresses and strains in the human pelvis.

The objective of this ongoing investigation is to quantitatively evaluate the effects of different insertion techniques and acetabular prosthesis designs on the strains in cadaver hemipelves. Initial work has led to the development of an automated computerized data acquisition system and customized loading fixtures. These innovative loading fixtures allow for simultaneous application of prosthesis loading and abductor muscle pull, simulating single leg stance.

Techniques that have been or will be studied during this investigation involve: perforation of the acetabulum with various size pilot holes; removal of varied amounts of subchondral plate and cancellous bone; use of keying holes of different sizes and placement; use of curette versus reaming; use of spacers to insure a uniform cement mantle; pressurization of the cement at implantation versus "hand-packing;" use of surface replacement prosthesis; use of protrusio rings, bone grafting, or wire mesh; and, modified acetabular cup types including metal backing, carbon fiber reinforced, attached spacers, and reconstructive techniques for deficient acetabuli.

Several general comments can be made:

1. The strain pattern in hemipelves without prostheses was consistent from specimen to specimen. Almost pure shear was observed.
2. The strain generally remained unaltered by the installation of standard prostheses if the acetabulum was not reamed or perforated by a central hole. The presence of the prosthesis appeared to be less significant than the disruption of the structure during installation.
3. A 10 mm central hole had a relatively small effect on the strain patterns. There was a shift in the distribution, with the bone anteromedial to the acetabulum being strained more highly. This shift was much more pronounced for bones with the larger (20 mm) central holes and further reaming. Further removal of bone by reaming elevated the strain levels more or less uniformly.
4. If all the cancellous bone was removed, the changes in strain from pre-implantation to post-implantation were quite variable.
5. The use of a protrusio ring to reinforce the acetabular implantation after moderate bone removal eliminated the anteromedial strain shift. Comprehensive strains were unaffected, but tensile and shear strains were almost uniformly increased by about ½ microstrain per Newton.
6. While curetting and reaming with a "cheese grater" caused significant increases in strains from the unaltered pelvis, they were not significantly different from each other.
7. The use of 7-4 mm keying holes (5 ilium, 1 ischium, 1 pubis) had a more pronounced effect on post-implantation strain than 3-12 mm holes (ilium, ischium, pubis).
8. No significant differences were observed with the use of moderate pressurization versus "hand-packing."
9. Spacers used to achieve a uniform mantle of cement led to greater increases in shear strain than "bottoming-out" the prosthesis. (This is contrary to initial thought and is being re-evaluated).
10. Preliminary results of the metal-backed cup indicate that its use reduced the amount of strain change.

Over the past 18 months significant modifications to the computer software and instrumentation have been implemented to streamline data acquisition and post-processing. New fixturing has been developed to allow for the use of a newly acquired Universal Testing Machine that will allow for better control of loading rate which is very important in the testing of these biological tissues.

Vascular Responses to Hip Replacements

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Sponsor: National Institutes of Health
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We have two major objectives for the coming year. First, we will continue work with our canine model, in which we seek to correlate the very characteristic damage induced at venous confluences by hip replacement surgery with the responsiveness of venous smooth muscle and with the architecture of venous confluences. Second, we will extend monitoring of venous diameter by ultrasound to veins of persons undergoing hip replacement surgery, and will examine confluences of human veins harvested from the healthy proximal portion of freshly amputated legs.

Our specific aims and the methods to be used follow:

1. To continue to investigate the responsiveness of canine venous smooth muscle in vivo by the noninvasive observation and recording of venous diameter by a specially adapted ultrasound instrument. The instrument has two electronic gates. The first picks up the falling edge of the peak generated by the near wall, and the second, the rising edge of the peak generated by the far wall. The distance between is calculated and displayed continuously, and an analog signal is taken to a strip chart recorder. We will continue to use specific inhibitors to identify vasoactive substances released or generated during hip replacement surgery.

2. To investigate ex vivo the responsiveness of jugular and femoral vein smooth muscle by the use of vein strips in an isometric tissue bath system. This approach was added since the last progress report and has provided quantitative information on the potential of these veins to develop tension in response to vasoactive substances.

3. To complete light microscopic studies of the architecture of the area at which side branches join jugular and femoral veins (confluences). Vein segments that have been examined by scanning electron microscopy are detached from the stubs and small areas containing a confluence embedded in plastic for serial 10 μ thick sections. Sections are stained, examined, and photographed by light microscopy.

4. To extend our monitoring of venous diameter to patients before and during hip replacement surgery.

5. To study the architecture of human venous confluences by use of veins harvested from the limited healthy proximal portion of amputated legs.

[See also **VI. Biomechanics**, **A. Joint Studies**, **2. Lower Limb**, Evaluation of Joint Loadings in the Use of Walking Aids in Total Hip Replacement, and **VII. Wound and Fracture Healing**, A Study of Intertrochanteric Fracture Fixation Methods]

Total Surgical Replacement of the Human Hip Joint

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

This study is directed to the evaluation of porous materials as a method for fixation of total joint replacement prostheses. An experimental canine total hip replacement model is used (i) to evaluate the abilities of different types of porous composites to provide satisfactory fixation and (ii) to study resulting bone remodeling in the femoral cortex and acetabulum. In a canine total knee replacement model, various methods of initial stabilization are evaluated in their ability to sustain satisfactory fixation. Metal ion release from porous materials is studied with cobalt-chrome porous composites made from powder metallurgy techniques and titanium composites made by fiber metallurgy.

The carcinogenic potential of materials used for porous applications is studied in rats, comparing the alloys in solid and porous composite forms. The potential of hydroxyapatite and electromagnetic stimulation to enhance initial bone formation into porous titanium composites is evaluated in a canine model by histology and mechanical testing. In a similar canine model, disodium etidronate is evaluated for its effects on early bone ingrowth into porous titanium composites.

The Efficacy of Radiolucent Low Modulus Total Hip Surface Replacement

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The purpose of this project is to investigate the potential of using a radiolucent, low-modulus, surface replacement as a prosthesis for the hip. The radiolucent aspect of the prosthesis offers the advantage of being able to visualize the bone underneath the femoral component. The low modulus of the femoral component surface replacement is hypothesized to transmit stress to cancellous bone of the femoral head in a more physiologic manner than would be obtained with a metallic component. From that aspect then, this is a bone remodeling study. The low-elastic modulus (pyrolytic carbon) femoral component is to be compared directly to high-elastic modulus prosthesis of cobalt chromium to determine the effect on the bone of the femoral head and neck.

The research methodology includes a series of comparisons of the bone remodeling of the natural femoral head, a carbon surfaced femoral head, and a cobalt chromium surfaced femoral head. The first series of eight dogs was a comparison between the normal femoral head and the carbon surfaced replacement femoral head. These dogs are now 17 to 35 weeks post-surgery. One of the dogs has been sacrificed due to loosening of the acetabular component. The direct comparison of the carbon surface replacement to the high-modulus cobalt chromium surface replacement is underway. Three dogs have undergone bilateral hip surface replacements, and more dogs are scheduled at regular intervals. For a comparison of these two types of surface replacements to the normal femur, finite element analysis is planned. Loading conditions for the femoral head in vivo have been determined, and preliminary studies using finite element analysis have been performed. The data from the finite element studies will be compared to the histological results obtained from sections of the femoral heads of these dogs after sacrifice.

In an attempt to maximize the data obtained from this series of dogs, quantitative bone densities underneath the carbon surface replacement have been obtained in vivo through the use of the research computerized tomographic scanner (CT scanner) at the University of California in San Francisco. Longitudinal studies of the bone density of the carbon surface replacements are underway. Use of phantom densities correlated with bone permit a quantitative absolute measurement of the bone densities, as well as the comparison of bone density with time to the normal femoral head. Studies have been started on the carbon surface replacement of the dogs with the cobalt chromium heads on the contralateral side. Although quantitative data will not be obtainable from the bone underneath the cobalt chromium surface replacement because of the X-ray shielding caused by the cobalt chromium, data can be obtained from the contralateral carbon surface replacements by avoiding overlap of the CT scan X-ray beam with the metallic component. CT scan densities are being measured for the normal contralateral sides in the unilateral hip surface replacement study.

It is expected that this study will reveal cancellous bone remodeling, which is indicative of the mechanical stress environment surrounding the cancellous bone. It is expected that, within the next 6 months, a sacrifice of the dogs that have undergone unilateral hip surface replacements will begin and histological data will be forthcoming. It also is anticipated that completion of the implantation of the bilateral hip surface replacement will be accomplished. CT scan studies at that point can be confirmed by the histologic data which is obtained from sacrifice.

Total Hip Implant Biotelemetry

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The long-term clinical success of total joint replacement depends on the ability of the bone-implant system to withstand the forces applied to it. Mechanical complications of implant breakage, cement fracture, skeletal loosening, and component wear are directly related to the transmission of these forces across the joint. Explicit data on the magnitudes and directions of these forces during normal activities are lacking in the literature.

This report is a collaborative effort involving the Research Service of the Wadsworth VAMC, the UCLA Biomechanics Research Section, and the Jet Propulsion Laboratory in Pasadena. The express objective of this project is the design and development of a special total hip femoral component which will contain within it a miniaturized biotelemetry system capable of broadcasting signals received from strain gauges mounted within the neck of the prosthesis.

The prosthesis will be inductively powered by an external coil, thereby eliminating the need for internal batteries or connecting cables. These strain readings will be analyzed by computer and combined to display the three force components and the magnitude and orientation of the resultant force vector acting on the head of the prosthesis. The present project is directed toward the design of the implant, refinement of the telemetry system performance, development of the power induction system, assembly of a data recovery system, a mechanical testing program designed to assure the structural integrity of the implant, and, finally, a leak test program to assure the hermeticity of the total system. The experience of the Jet Propulsion Laboratory will be used to supply the microelectronic modules as well as the performance of the hermeticity program, while manufacture of the prostheses and structural tests will be carried out in the biomechanical testing facilities at UCLA. After instrumentation, some partial and some complete, the components will be subjected to static and fatigue loading patterns in vitro to establish factor of safety margins. External gauges will be utilized on some units to verify the calibration and operation of the internal instrumentation.

Progress to Date—Six partially machined T-6A1-4Vn prosthesis housings, one ball-neck unit, and integrated circuits were supplied to JPL for the initial instrumentation phase of the project. These deliverables have all been inspected and were found to be within acceptable limits of the specifications in most instances. Some of the semi-conductor gauges were found to be grossly misaligned, but are deemed salvageable through precise trimming operations. Broaching of the component necks for the strain gauge attachment is nearing completion. A slight delay in the bonding of the semi-conductor gauges has been encountered and assignment of task orders has been subject to personnel availability at JPL. This is expected to result in only a minor delay in the return of the static load unit to UCLA for initial structural testing.

Major tasks to be completed by JPL for the remainder of the first project year will be to: (i) develop a procedure for attachment of the semi-conductor gauges to the titanium inner neck surface, (ii) deliver to UCLA a sealed and partially instrumented prosthesis (static load unit), (iii) perform secondary seal tests on the static load unit, and (iv) initiate an accelerated life test of 12 telemetry submodules.

The major tasks for UCLA for the remainder of the project year are: (i) to design and manufacture the fixtures to house the static load unit for mechanical testing, (ii) to instrument the outer neck surface of this unit and to perform calibration of the internal gauges, and (iii) to load the unit to static failure to determine the ultimate loads and stresses.

All test data gathered from this project will be presented to the Veterans Administration Human Use Committee for their consideration and approval before proceeding into the patient implantation phase of the program■

C. Knee

Interaction of Total Knee Replacement Geometry with Knee Ligaments

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Rehabilitation Engineering Program

Loosening of the tibial component is a major factor in the failure of total knee replacements (TKR). This project is intended to identify ligamentous constraint forces which increase interface stresses to a level that may contribute to the loosening process and ultimate failure of the TKR. The resulting information from this project will form the basis for potential implant design changes, alterations of TKR surgical procedures, guidelines for choosing existing knee implant designs when faced with various clinical situations, and recommendations for improved rehabilitation and orthotic treatment of postoperative knee implant recipients. The current specific question to be investigated is whether or not the geometry of a knee implant's tibial component should allow retention of one, both, or neither of the cruciate ligaments. Two methodologies are being used to address this issue.

The primary phase of this project is to investigate the initial postsurgical state of the knee with TKR by experimentally using an electrogoniometer (and computer-based data acquisition system) and buckle transducers in a series of knee specimens. This will be done in conjunction with an analytical force analysis and finite element stress analysis to determine ligament and joint contact forces, as well as interface stresses (potential for loosening) for various existing ligament-TKR design combinations.

During this reporting period, the in vitro experimental system needed to perform that project phase was being synthesized. Improved buckle transducers were designed and are being built. A new specimen loading apparatus was designed, and its construction is nearly completed. An improved six-degrees-of-freedom electrogoniometer was built, as well as a mechanical calibration device. A microprocessor, A/D converter transducer amplifiers, and a floppy disc drive were purchased and interfaced. The appropriate data collection and computational computer software are nearly completed. Testing will begin soon, and will be carried out during the coming reporting period.

The second project phase involves development of an improved biplanar radiographic technique and application of the technique to predict in vivo ligament lengths and forces in human subjects with total knee prostheses during actual static joint load conditions. This information will help answer the above cruciate problem statement: keep ligaments if they are functionally load bearing, and sacrifice them if they are not. Work in this phase during the current reporting period has been directed toward the design of total-knee prosthetic components with extensions or markers that can be easily seen on biplanar X-ray films, and which will not compromise the insertion of the prosthetic components, as they will eventually be implanted in vivo. Preliminary component designs have been made and will be refined during the coming reporting period.

Prospective Clinical Study of the Kinematic Knee Design

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Rehabilitation Engineering Program

This is an ongoing project to study kinematic knee patients in an attempt to identify quantitative relationships between clinical data and the eventual outcome of kinematic knee replacements, and to evaluate the effectiveness of this particular prosthesis in eliminating pain and restoring and rehabilitating severely disabled individuals to normal, active lives. Data were collected from hospital and operating surgeon's files. Data included component type and patient history, as well as preoperative and postoperative physical, functional, and X-ray findings. Each case outcome received a grade, using the Hospital for Special Surgery Knee Evaluation scale. Finally, the development of radiographic radiolucent lines between implant, cement, and knee was recorded.

To date, 103 patient cases have been included in the study. Of these, initial statistical analysis has been performed on 92 cases. These cases have been followed up in an ongoing fashion in an attempt to achieve a minimum 6-month, 1-year, and 2-year followup. Several cases await complete long-term followup data.

In the future, efforts will center on attempts to determine via multivariate analysis the subtle relationships between procedure outcome and variables recorded. In addition, patients will be called back to determine the accuracy of radiolucent line size measurement.

Investigation of a Simplified Internal Knee Prosthesis

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Research and Development Service

The objectives are to determine the optimum means of transferring loads from press-fit implant components to the bone surface, and to design a press-fit total knee replacement for clinical application.

The first part of the study was to model the bone structure in terms of its geometry and the properties of the trabecular bone. Twenty distal femurs were embedded, sliced sagittally, and input to a graphics computer using digitizing. Software was developed to enable three-dimensional reconstruction at required viewing angles. An attempt was made to model certain parts of the femur using geometrical surfaces. From direct measurements, the posterior femoral condyles, the bearing surfaces from 15 to 135 degrees of flexion, were found to resemble spherical surfaces. This was confirmed in the computer, the mean error of points on the surface from a perfect sphere being only half a millimeter. Each femur was then expanded or contracted based on a standard m-1 width; equivalent profiles were then superimposed, and then a contour averaging program was written to reach an average. In this way, the 'average distal femur' was constructed.

The morphological and mechanical properties of the trabecular bone were studied, especially the bone close to the joint surfaces. A sample knee was sliced in the sagittal and frontal planes; cubes of bone were removed and thoroughly cleaned for scanning electron microscopy. The increased density of the bone close to the surfaces was clearly seen, especially on the tibia. The bones oriented generally perpendicularly to the bearing surfaces, along the lines of principal compressive stress, and were usually in the form of perforated sheets or plates separated by struts.

Thus, it appeared that, by removing minimum bone from the joint surfaces, load could be transferred from a metallic implant directly to the sheets and plates for maximum load support. However, to achieve this, accurate geometrical fit would be needed. This was tested for the upper tibia by loading flat metallic components onto bony surfaces prepared by level re-section in a band saw. Fuji film pressure patterns showed that the load was transferred through localized regions of the bone surface, a function of the bone stiffness and the flatness of the cut. In surgical practice it was clear that such local load transfer would generally occur. Cyclic loading tests were carried out to determine whether the areas of load bearing would increase with time. It was found that, while there was an increase, certain areas that were previously load bearing were no longer so, apparently due to subsurface trabecular failure. This supported a rehabilitation period with low joint forces to enable biological remodeling to achieve an adequate area of load transfer to avoid component sinkage.

A Press-Fit Total Knee, based on a direct interface of metal to bone with no cement or porous beads, was designed. The first of these was implanted in a patient in February 1984■

In Vivo Loading on Total Knee Joints

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The purpose of this project is to determine the in vivo loading data from total knee joint replacements. These new joint replacements will have incorporated within the body of the tibial components the required telemetry circuitry to telemeter seven channels of loading data from the device. These channels will be used to record the loads on the device, allowing for the determination of the three forces on the three moments on the tibial components■

Biomechanical Study of Total Knee Replacement

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The objective for the coming year is to continue studying the biomechanics of the knee joint with respect to patient function, prosthetic design, and internal joint mechanics. The specific aims are:

1. Complete the analysis of functional measurements collected on patients with the posterior stabilized total condylar knee, two designs of unicompartmental knee, and additional patients with an anatomical unconstrained design (Cloutier) of total knee. This analysis will be used to test our original observations on a smaller population, and to evaluate the influence of a posterior cruciate substituting device (the posterior stabilized total condylar).

2. Test further our hypothesis that the function of total knee replacement patients is related to the interaction between the design of the prosthesis and the function of the quadriceps muscles. This hypothesis will be tested by applying the previously developed mathematical models of the knee along with some cadaver tests for validation of the models.

3. Continue our prospective analysis of the high tibial osteotomy procedure by analyzing preoperative and sequential postoperative function at 1-year intervals following surgery. This patient population will be evaluated during level walking and stair climbing.

The methodology for the functional studies utilizes a computerized optoelectronic system and force platform for kinetic measurement of level walking and stair climbing. Patients will be measured while walking over a range of speeds and while ascending and descending stairs. The model of the knee joint employs a numerical procedure to predict muscle forces based on external measurements of joint moments and motion. The model incorporates kinematic features of the knee that permit us to test for mechanical interactions between muscles, soft tissue, and kinematics of the articulating surfaces■

[See also **V. Functional Assessment**, The Efficacy of Surgical and Rehabilitative Procedures of the Knee]

IV. Spinal Cord Injury

A. General Rehabilitation

A Research and Demonstration Project for Rehabilitation of Paraplegics in Madras

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Background—In developing nations such as India, the management of (SCI) patients is replete with difficulties at every stage of care because of the paucity of trained personnel and the meager facilities.

The proposal for this project was mooted in 1969 and finally started in 1978.

Aims and Objectives

1. The main aim of "Paraplegia Project, Madras" has been to develop simple methods of care of SCI patients in a general hospital setting without reliance on expensive equipment. While the need for and importance of centers exclusively devoted to a SCI population is recognized, establishment of such centers is unattainable in vast tracts of the world for several decades to come. In contrast, the methods of care at Government Hospital, Madras, if found effective and useful, have the merit that they can be immediately transferred as appropriate technology to other parts of India, and to other developing nations as well.

2. The Paraplegia Project was established for total care of SCI patients in Madras and adjoining districts within a radius of 200 miles. The multidisciplinary care of the patients, highlighted by a monthly Ward Rounds of all specialists, brought rich dividends by decreasing the mortality and morbidity. It increased function in terms of independence of SCI patients, and it decreased the duration and cost of acute and rehabilitation care.

Findings

1. Three hundred system cases and 200 non-system cases have been treated at the project. The final report is in preparation. It is hoped that the findings will highlight the place of "the art of the possible" in the care of SCI patients in developing nations.

2. SCI patients at Madras were mostly males in their second to fourth decades of life. The injuries were sustained mostly in villages; manual and agricultural laborers were affected mostly. Falls from trees or falls into wells have been the commonest causes of injury; road accidents have accounted for fewer than 10 percent of cases. Cervical spine has been involved in about 50 percent of cases.

3. Most of the patients were treated by conservative methods; operative treatment was done in a few cases where indicated.

4. Over the years there has been a significant reduction of complications, with gratifying results in the care of skin and bladder.

5. Psychiatric workup and counseling have added a new dimension to the care of SCI patients in the last year.

6. Mobility aids were given to nearly all needy patients through the help of governmental and social welfare agencies.

7. Vocational rehabilitation for self-employment with the aid of bank loans has enabled many patients to start anew.

The Madras Method of Acute Care of Flexion Injuries of Dorsal and Lumbar Spine.

The "Madras Method" of postural reduction with two pillows behind the apex of the gibbus has been found to be eminently suited for acute care of flexion injuries of the spine below the level of the fourth dorsal vertebra. The merits of the method are the reduction of the fracture or fracture dislocation, prevention of skin and lung complications, the fact that turning can be done by a single person, and, above all, its simplicity.

Two pillows as wide as the bed are arranged as a wedge at the level of the gibbus. The level of the gibbus is identified and a circumferential line is marked with gentian violet over the middle of the upper of the two pillows. The patient is positioned over the pillows so that the two lines, i.e., those on the patient and on the upper pillow, coincide. With the patient supine, the wedge of the pillows reduces the fracture and, in the course of a few hours, restores the alignment to an acceptable degree. The patient is turned every 2 hours by an attendant using the upper of the two pillows as a lever. No specially qualified person is required for such turning; anyone can be taught to do it. While the patient is in lateral recumbency, a large sandbag is laid over the back to restore the curvature of the spine.

Summary—When viewed in the context of the enormity of the problem, with practically no facilities available for the care of SCI patients, the achievements of the Paraplegia Project in Madras have been praiseworthy■

Demographic and Economic Studies

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Sponsor: American Paralysis Association

Detailed statistical data on the incidence and prevalence of spinal cord injury in the United States will be collected and evaluated to determine the direct and indirect costs of SCI, both to the paralyzed individual and the general public (through government expenditures). Cost effective approaches to reducing the incidence of injury will be highlighted. It is hoped that such data will provide an effective economic argument, demonstrating the urgent need for increasing current research expenditures devoted to the cure of spinal cord related injuries■

Interactive Video Education System for Rehabilitation

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Problem—In order to facilitate a return to active and fulfilling lives, spinal cord injured patients, and those associated with their care, need to learn a wealth of information. Rehabilitation is largely an educational process where routine issues in life are re-examined and new approaches learned. Information about activities of daily living, vocational opportunities, and recreation are just a few of the important concerns of an effective rehabilitation program. This information should be available to disabled users so that they can independently access it when they need it or are ready to learn it.

Ideally, a rehabilitation program should be flexible enough to accommodate the variety of needs and learning rates among the patients. Such flexibility could also allow individuals to govern their own pace through the rehabilitation process, further encouraging their independence and personal initiative.

For the physically disabled, however, their ability to interact with conventional educational aids may be impaired. This constraint indicates the need for an interface which brings the material within their range of perceptual and motor abilities. This interface needs to be incorporated into a system that effectively presents the educational information to the user population.

Significance—This system promises to be cost effective while providing greater access to information. Successful learning is an experience in which one gains information and an enhanced sense of ability to deal with new situations. A spinal cord injury rehabilitation program using this system could provide patients with information, a model for coping with new situations, and the positive experience of living independently through learning. This system also has potential applications in educational and industrial training environments.

Background—Classroom instruction and one-on-one sessions with the health care staff are the traditional rehabilitation learning experiences in a spinal cord injury unit. However, limitations of time, facilities, and personnel may make needed information and instruction unavailable just when the patient is most ready to learn. Video is a convenient and effective medium for instructional rehabilitation that is currently widely used. However, many disabled patients are unable to independently operate video playback equipment, placing them in a position of dependence on the health care staff. The need to address this problem was initially identified by a clinical nurse specialist in the Spinal Cord Injury Center (SCIC). The development effort in this project has involved RR&D, SCIC, and graduate mechanical engineering students at Stanford.

Hypothesis—We hypothesize that a combination of interactive video technology and computer-aided instruction methods can be used to supplement and enhance the learning experience of the patients in a rehabilitation program. Further, we believe that the rehabilitation process is significantly augmented by giving patients the opportunity for independent self-instruction and the use of sophisticated assistive aids which encourage independence.

Approach—Our objective is to provide the disabled community with 24-hour independent access to video

information. This involves identifying and consolidating relevant video educational material and enabling all users to interact with this information resource. The user population includes high-level quadriplegics, who have no use of their hands but normal head and vocal control. Able-bodied users, such as family members and health care staff, should also be able to interact naturally with the system. The system will be concurrently developed and evaluated in order to design it to best serve the needs of its users.

Status—A prototype system has been constructed to demonstrate the concept and undergo preliminary evaluation. In order to make the system accessible to persons with high-level spinal cord injuries, it is designed to be automatically activated by the approach of a user. Voice input is used, since disabled and able-bodied users can operate this interface with equal ease.

The system is designed to be functionally flexible and easily reprogrammable, allowing us to modify, add, and experiment with different features. It also monitors its own use and stores pertinent data. For example, for each learning session, the computer records the date and time that the system is activated, elapsed time spent with the system, sequence of video programs viewed, and performance characteristics of the voice interface. This information provides a quantitative measure of how the system is performing and being used and will help us better understand the needs of the users. The system is assembled in a self-contained package that can be readily transported to different sites for demonstration and clinical evaluation.

We plan to continue to evaluate and develop this prototype system. Information gathered from the evaluation of this prototype will be used to design a more comprehensive system. This system might incorporate interactive videodisc technology to provide faster access to more video material. We plan to add more interfaces (joystick, touch screen, etc.) in order to allow users to choose the most efficient mode of input for them. Providing this selection of interfaces would also enable us to compare and evaluate their performance. We also hope to include new interactive video programs which would be relevant to the needs of the users.

Outcome Studies Pertinent to the National Spinal Cord Injury System

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This project encompasses four studies, three retrospective and one prospective, aimed at providing additional evidence about the effectiveness of the National Model Spinal Cord Injury System Project administered previously by RSA and currently by NIHR.

The three retrospective studies capitalize upon existence of the common data base established by the national systems. One study is an attempt to demonstrate that the highly advanced system of care practiced at the Royal Perth Hospital in Australia results in better patient outcomes than obtained in the less advanced care systems in the U.S.A. The second study is concerned with documenting post-rehabilitation outcomes for quadriplegic patients who, at discharge from inpatient rehabilitation, require ventilatory assistance. The third study attempts to clarify effects on patient outcomes of delaying patients' transfer from an acute care setting to a rehabilitation setting.

The prospective study will compare the outcomes of two groups of patients. One consists of patients whose acute and rehabilitation care was provided by the Texas/South Central Regional Spinal Cord Injury (T/SCRSCI) System. It is comprised of four acute care hospitals in the Houston-Galveston area and of The Institute for Rehabilitation and Research (TIRR) as the rehabilitation setting. The second group will consist of patients who were discharged from the same four acute care hospitals but who did not receive rehabilitation services at TIRR. Data for TIRR patients are being obtained in a companion project, entitled Assessment, Development, and Clinical Applications of Strategies to Coordinate Services for Spinal Cord Injured Clients After Discharge. Data for non-TIRR patients will be obtained during home interviews using an adapted form of the interview used in the companion project.

Status to Date—During the project's first year, the U.S.-Australian systems study was completed, and an article has been submitted for publication. One data set reflected experience with 65 consecutively admitted patients whose care during 1979 and 1980 occurred in the spinal cord unit at the Royal Perth

Rehabilitation Hospital in Perth, Western Australia. The second data set pertained to 1606 U.S. patients who had been cared for in one of the regional systems during the same 2 years. The results indicate that decubitus ulcers, atelectasis, pneumonia, pulmonary emboli, ulcers of the gastrointestinal tract, and heterotopic ossification all occurred more frequently in the U.S. group. This was especially true of decubitus ulcers and urinary tract infections. These outcomes demonstrate that the sooner spinal cord injured patients are referred to a center capable of meeting all their needs, the less likely it is they will develop complications that slow rehabilitation progress.

The studies concerned with post-rehabilitation outcomes for ventilatory dependent quadriplegics will continue during the second year, as will the prospective study comparing outcomes for system and non-system patients■

Development of a Reconditioning Exercise Program for Patients with Paraplegia

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The overall purpose of this project is to develop a testing methodology and to evaluate an exercise training program for the physical reconditioning of the patient with paraplegia. The expected outcome is the formulation of guidelines for the prescription of exercise and the documentation of the effects of physical conditioning programs for the patient with paraplegia. Male paraplegics between 18 and 50 years of age, free from disorders that contraindicate relatively high levels of exercise, and who have reached a suitable status in their rehabilitation process, will be selected for participation in the project.

A minimum of five patients is to be studied in each of five categories of training modalities. Each participant initially will be administered an exercise stress test consisting of interviews, blood sample for biochemical analyses, resting ECG, physical exam, and a graded arm ergometry test using an interrupted steady-state protocol. Expired gas will be collected during the last minute of each exercise phase. The training program modalities will consist of prescribed unsupervised exercise at home or exercises in a gamefield especially designed for wheelchair patients. Other patients will perform prescribed exercise under supervision in the laboratory or gamefield. Initially, the exercise period is for 5 to 10 minutes increasing to 20 to 25 minutes with training. Training will be 3 days per week for 8 to 12 weeks. After training, the patient will be subjected to a post-training study in which the testing of the first study will be repeated.

Status to Date—This first year has been directed at achieving a series of tasks that include: testing of an arm ergometer developed by the TIRR Rehabilitation Engineering Center, testing of an expired gas collecting system, evaluating methods of ECG recording during arm exercise in the laboratory and in the outdoors gamefield, developing a procedure for measuring leg blood pressure during exercise with the arm, establishing a baseline of biochemical measurements relating to exercise, and developing historical documents for recording clinical/socioeconomic historical data and a computer data file system for storing data for subsequent analyses. These tasks have been successfully accomplished with two exceptions: (i) telemetry of ECG under outdoor gamefield conditions, which is subject to interference from citizen band radio transmissions; and, (ii) measurements of blood lactate during arm ergometry, which was impractical on a cost/effort basis with equipment available at the beginning of the project. Solutions to these problems are being sought.

The methodology for assessing the cardiovascular tolerance to physical work with arm exercise has been well established. It has been successfully applied to 16 untrained paraplegic males, some more than one time, and to six healthy male subjects tested in the same manner to obtain comparative data. One well trained paraplegic male also has been tested. The healthy subjects are currently being trained in the use of the wheelchair in the gamefield events for subsequent determinations of the energy requirements of such events■

Assessment, Development, and Clinical Applications of Strategies to Coordinate Services for Spinal Cord Injured Clients After Discharge

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There are three major project objectives: (i) to assess current strategies employed after discharge to achieve psychosocial adjustment and productive lives for spinal cord injured persons, (ii) to develop and test new strategies or refine current strategies to enhance outcomes postdischarge, and (iii) to facilitate the integration of new and tested strategies into the service delivery system at The Institute for Rehabilitation and Research (TIRR) and disseminate the strategies to other appropriate sites. Methods include interviewing rehabilitation professionals and spinal cord injured clients to assess needs and resources, collaborating with service providers to develop and test improved strategies to address unmet needs, and assisting integration of the improved strategies into the service delivery system. Approximately 150 spinal cord injured persons over 14 years of age who were admitted to TIRR for comprehensive rehabilitation from 1979 to the present will be interviewed. Rehabilitation professionals from a variety of disciplines will be interviewed and/or serve as an advisory committee.

The benefits expected from this project include meeting needs early so that compounding problems can be avoided, utilizing resources efficiently by tailoring programs to meet the actual needs of clients, and improving rehabilitation outcomes by providing appropriate services.

Status to Date—A protocol was developed for interviewing rehabilitation professionals. Eight professionals from six rehabilitation disciplines were asked to describe the needs of spinal cord injured clients following discharge, the resources available to meet those needs, and the systems for linking the clients with the appropriate resources. Eight broad categories emerged: health, activities of daily living, living arrangements, vocational, psychosocial, transportation, financial, and societal issues and policies. The list of needs described by the professionals was used to develop an interview protocol for use with clients to determine needs, utilization of formal and informal resources, how they found out about resources, satisfaction with resources, and special difficulties encountered in meeting their needs. A list of approximately 600 spinal cord injured clients eligible to participate in the study was obtained.

The protocol for interviewing clients currently is being refined to ensure that all essential information can be obtained in an efficient manner. The protocol is being thoroughly pilot-tested with a number of subjects. During 1984, client interviews will be conducted, and arrangements have been made to work collaboratively with the National Spinal Cord Data Base and the Research and Training Center project on Outcome Studies Pertinent to the National Model Spinal Cord Injury System■

Documenting and Utilizing Programs to Provide Community Adjustment and Independent Living Services for Persons with Spinal Cord Injury

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The purpose of this project is to collect and maintain information about independent living and community adjustment programs that serve spinal cord injured people, to provide an effective means of communicating new ideas and experiences between individuals operating these programs, and to provide access to a dependable source of technical assistance related to these programs.

Non-experimental survey methodology is being used. The data are summarized in frequencies according to specified categories of interest, and some correlational studies are being done to determine trends in independent living program development. Data from project surveys are used to assess the types of services being provided for persons with spinal cord injury.

In order to facilitate use of the information developed, the project maintains a telephone communication network with all the extant independent living programs and approximately 150 additional individuals. Knowledge transfer strategies depend on the specific topic or set of information, but they usually involve extensive reviews of existing literature, interviews with independent living program administrators, staff members, consumers, and supplementary

reviews by additional experts, both in and out of the independent living field.

Status to Date—A survey instrument has been designed and distributed, a computerized data base management system has been designed, and a tentative report format has been developed. Work on all tasks is underway as scheduled. Project staff have responded to several hundred mail and telephone inquiries. On site training has been provided in Houston and Dallas, and a series of additional training programs are being planned. One book chapter has been published and two articles have been prepared for professional journals. Presentations have been made at meetings in Houston, Dallas, Denver, and Charlotte, North Carolina. Efforts have been made to coordinate training with the Houston Center for Independent Living, and feedback has been obtained relating to the effectiveness of project efforts.

The work plan for the next grant period emphasizes analysis of the survey data. Other effort will be devoted to data base updates, information dissemination, training, and networking■

Vocational Evaluation for Quadriplegics with a High School Education or Less

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The project objective is to develop a vocational evaluation process that will expand the vocational options for spinal cord injured persons who are quadriplegic, who have a high school education or less, and who have either a limited work record or a job history incompatible with current functional limitations.

Methodology involves: (i) identifying and documenting jobs that can be performed by the described population group; (ii) conducting a comprehensive review of existing vocational assessment tools and determining relevance of tools to assess potential of quadriplegics; (iii) selecting and organizing a meaningful process; (iv) incorporating the model vocational process into the Vocational Department's service delivery program; and, (v) evaluating the effectiveness of the model evaluation process.

The expected outcome of this project is the establishment of a more effective and realistic vocational evaluation process that can be used to assess the job potential of quadriplegics. The project also may have implications for other disability groups with severe physical impairments.

Status to Date—This project is continuing in the developmental phase. Of 6050 jobs that have been reviewed, 162 have been judged by the project staff to be options for quadriplegics with a high school education or less as follows:

Occupational Category	No. of Job Options
Clerical	78
Service	20
Agricultural and related	0
Processing	18
Machine Trades	46

A total of 334 vocational assessment tools have been reviewed. Of this total, 55 commerical work samples, 18 noncommercial work samples, and 15 psychometric tests were determined by the project staff to be within the physical capabilities to be performed by quadriplegics.

Activities planned for the forthcoming year include: (i) identification and documentation of job options in bench work, structural, and miscellaneous occupations; (ii) continuation of review of assessment tools; (iii) selection of assessment tools that are applicable to measuring potential for identified job options; and (iv) organization of vocational evaluation process■

B. Medical Treatment

Determinants of Renal Function Alterations During Long-Term Follow-Up in Patients with Spinal Cord Dysfunction Using Radionuclide Procedures

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Background—The relationship between spinal cord injury (SCI) and urological disorders is well established. No other group compares with SCI patients in terms of severity and morbidity of urinary tract infections (UTI). The UTI and the other complications associated with a neurogenic bladder, such as vesicoureteral reflux, bladder cellules, diverticuli and trabeculae, urethral strictures and abcess, calculi, etc., often result in renal disease and the ultimate renal failure which is a leading cause of death among SCI patients. Thus, continual long-term follow-up of these patients is necessary. Most SCI centers utilize excretory urography (EXU) coupled with blood urea nitrogen or serum creatinine measurements for this purpose.

Earlier studies from this laboratory have shown that measurement of effective renal plasma flow (ERPF) with a comprehensive renal scintigraphy procedure (CRSP) is preferable to EXU for several reasons. However, there were several discrepancies between EXU and CRSP results in some patients. This study was designed to explore these discrepancies and evaluate the clinical significance of minimal CRSP and EXU changes after SCI.

Hypotheses

1. Anatomic changes of the kidney demonstrated by excretory urography (EXU) are clinically useful in the long-term management of the urinary tract, even if unaccompanied by functional alterations.

2. Functional alterations in the kidney demonstrated by comprehensive renal scintigraphy procedures are clinically useful in the long-term management of the urinary tract, even if unaccompanied by anatomic changes.

3. Normal CRSP parameters differ significantly in spinal cord injury patients and other types of patients.

4. Measurement of the glomerular filtration rate (GFR) or filtration fraction provides clinically useful information about SCI patients having discordant EXU and CRSP findings.

Methodology—All SCI patients with neurogenic bladders are evaluated with renal scintigraphy during their initial hospitalization and at their annual follow-up examinations. Those with a significant decrease in ERPF are evaluated with EXU as well. KUB X-rays are taken of each patient to detect renal or bladder calculi. Blood chemistries and urine analysis are performed as deemed necessary by the attending physician. GFRs are measured by renal scintigraphy. Those patients who receive both EXUs and CRSPs have these tests graded as normal or abnormal, and the concordance of these test results are determined. In the case of discrepancies, other test measurements, such as GFR or serum creatinine levels, are used to determine the validity of CRSP and EXU findings. The mean and standard deviation for ERPF and other scintigraphic parameters in SCI patients are compared on an age- and sex-adjusted basis with results from renal transplant donors prior to nephrectomy.

Preliminary Findings—We have performed over 2000 CRSPs. Most (1839) were on patients entered into the study. Although no new patients are being entered at this time, we are continuing to follow those patients already entered.

Since the last report, we have measured GFRs in 20 patients using the 5-minute camera/computer technique combined with a single blood sample collected at 180 minutes. In addition, we have refined the computer program used in the study, making it more automatic, and revised background correction methods. We also have revised slightly the formula for calculating GFR from the single 180-minute sample, and developed an algorithm for use when blood samples are not drawn at exactly 180 minutes, but rather in the interval ranging from 146 to 235 minutes. Comparisons have been made between differential and total GFR values and differential and total ERPF values, with much better agreement than in the previous group of patients. We have performed duplicate GFR measurements in three patients at 1-week intervals and found no statistically significant differences in total GFR, relative function on either side, or differential GFR values.

Because we have refined the limits of expected values for CRSP parameters in spinal cord injury patients, we have found fewer and fewer discrepan-

cies between CRSP results and EXU results. Moreover, we are performing fewer EXUs than originally expected, since we are seeing fewer people whose renal status requires, or even allows, excretory urography to be performed. We will, in the coming year, focus our attention on those patients who have discordant CRSP and EXU results, possibly even paying their expenses to return for follow-up examination, if they have not returned since the initial discordance was discovered. At this point, our distinct impressions are that past discordances resulted from inadequate information on expected limits for CRSP parameters in spinal cord injured patients. The study will be completed in May 1985.

Effectiveness of Prophylactic Antimicrobial Therapy in Patients with Spinal Cord Injury

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Background—Bacteriuria is the most common complication of spinal cord injury (SCI). Patients with indwelling catheters may all be safely assumed to have continued bacteriuria. The advent of intermittent catheterization programs (ICPs) has resulted in a dramatic decrease in the incidence of bacteriuria in these patients, but even successful ICP graduates are at very high risk for contracting bacteriuria. The present study was designed to determine whether any of several prophylactic antimicrobial treatments could reduce the incidence of bacteriuria in SCI patients who were free of indwelling catheters.

Hypothesis—Bactrim, Macrodantin, Hiprex, Neg-Gram, and ascorbic acid given at prophylactic levels are superior to no treatment in preventing urinary tract infections in SCI patients without indwelling catheters.

Methodology—SCI patients with neurogenic bladder constitute the study population. Neurologic level and extent of lesion are documented. Upon entering the study, a urine culture, colony count, and sensitivity are obtained and appropriate antibiotic therapy initiated. After sterile urine is achieved, subjects are assigned by ordered sequence to one of five prophylactic treatment regimens. Cultures, colony counts, and sensitivities are obtained weekly while the subject is hospitalized. The study is discontinued if and when it becomes necessary to replace the indwelling catheter, if the patient becomes reinfected, or if continued follow-up becomes impractical. The average number of weeks each patient remains infection-free is being calculated, and the differences between each drug's ability to maintain a sterile urine is being determined.

Preliminary Findings—Bactrim was the drug found to be most effective for prophylactic treatment of urinary tract infection in spinal cord injury patients; ascorbic acid was the least effective. However, it should be noted that the median infection-free period was only 11 days for Bactrim. Current evidence suggests that none of the drugs tested, including Bactrim, was particularly useful in preventing urinary tract infections in these patients at the doses studied. It should also be noted that patients given ascorbic acid generally had fewer infection-free days than control patients. The study concluded on July 1, 1984.

Urinary LDH Fractions for Localizing Site of Urinary Infections in Patients with Spinal Cord Dysfunction

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Background—There is a marked difference between the clinical significance of cystitis and pyelonephritis. Several procedures have been proposed to distinguish between the two. One common method, ureteral catheterization, is expensive, highly invasive, and not without attendant risk. It is generally acknowledged that there is a need for a simple laboratory test capable of distinguishing between upper and lower urinary tract infections. This project has examined lactase dehydrogenase (LDH) isoenzyme patterns of ureteral urine in an attempt to determine whether alterations in them can be used to differentiate between upper and lower urinary tract infection (UTIs) in spinal cord injury (SCI) patients.

Hypothesis—The urinary LDH isoenzyme patterns of SCI patients with upper tract infections are signifi-

cantly different from urinary LDH patterns of SCI patients whose urinary tract infections are confined to the bladder.

Methodology—Ureteral urine specimens, bladder urine specimens, and prostatic secretions have been obtained from a series of male SCI patients. Colony counts, culture identification, and antibiotic sensitivities have been performed on all specimens. Total LDH and the relative proportion of each of the five LDH isoenzymes have been determined. Ultimately, total LDH and relative LDH isoenzyme concentrations will be compared statistically in patients with (a) bladder infection only, (b) kidney and bladder infections, (c) prostate and bladder infections, and (d) kidney, bladder, and prostate infections.

Preliminary Findings—To date, we have studied a total of 20 patients, 15 of whom have had total LDH assays. In these patients, bladder urine, urine from the right and left ureters (separately), and prostatic secretions were analyzed for total LDH and relative amount of LDH in each of five subfractions.

Our results to date suggest that neither the level of total LDH nor the relative proportions of the LDH subfractions in bladder or ureteral urine or prostatic secretions are diagnostic of an upper tract infection. In practical terms, even if total LDH levels or subfraction proportions in ureteral urine were diagnostic for an upper tract infection, current practice of culturing this urine for bacterial growth and antibiotic sensitivity would be less expensive, more direct, and therefore preferable to measuring total LDH levels or subfraction proportions. Increasing the number of patients studied is very unlikely to alter these provisional conclusions, since we have encountered both false positive and false negative results, and these must be considered even in the light of studies on additional patients■

Didronel in the Prevention of Heterotopic Ossification Following Spinal Cord Injury: Determination of an Optimal Treatment Schedule

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Background—The surprisingly high incidence of heterotopic ossification (H.O.) following spinal cord injury (SCI) and/or other severe neurologic injuries or diseases suggests that it is a frequent complication of patients admitted to rehabilitation programs. When its severity limits joint motion and exacerbates the disability, impaired function may be of such degree that it limits ambulation or wheelchair independence, or it may even impair mobility to the extent that the patient must remain bedfast. Protracted periods of confinement in bed or in abnormal sitting postures in wheelchairs may cause the formation of pressure sores. A drug, Didronel (etidronate disodium), has been shown effective in preventing H.O. when administered prophylactically after spinal cord injury. Since the occurrence of H.O. frequently leads to extensive and costly hospitalizations, as well as to interruption of the vocational rehabilitation process, it is warranted to pursue studies that directly impact on prevention of H.O. rather than to study the complication after it has occurred.

Hypotheses—(i) There is an optimal time post-injury when Didronel therapy should be initiated to achieve the maximal prophylactic effect; (ii) there is an optimal duration of Didronel therapy that will yield a maximal prophylactic effect; and (iii) there is an optimal dosage of Didronel that will yield a maximal prophylactic effect.

Methodology—The study population is being made up of patients admitted to the UAB-Spinal Cord Injury Care System between 0 and 120 days post-injury, whose lesions are neurologically complete (or neurologically incomplete with residual function less than a Frankel Classification of "motor non-functional"), who are at least 16 years of age, and who are not pregnant. Patients in the series are subcategorized into early and late treatment groups, and further divided into 3- and 6-month administration groups. X-ray films of

both hips are obtained 1 day prior to initiation of Didronel therapy, at the end of each treatment period, and 1 year post-injury.

Preliminary Findings—One hundred thirty-eight subjects have been entered into the study. Substantially more subjects have been entered into the Early Treatment Group (15 to 44 days post-injury) than into the Late Treatment Group (45 to 120 days post-injury). The reason for this is that most SCI patients are admitted to this center well within 44 days of injury, since our Spinal Cord Injury Care System emphasizes early admission. It is imprudent to delay transfer admissions solely for the purpose of being able to enter a prospective patient into any clinical study. In this case, it would be considered particularly imprudent, since the agent, disodium etidronate, has been proved effective in the early prevention of heterotopic bone formation. However, if patients are admitted to our center 45 or more days after injury, they are entered into the Late Treatment Group routinely, if they meet all other selection criteria.

A total of 85 patients/subjects have been assigned to the Early Treatment Group. The remaining 53 patients/subjects met Late Treatment Group entry criteria and have been thus assigned. Those patients/subjects in the Early Treatment Group were further subdivided into comparably sized sub-categories with approximately half receiving drug therapy for 90 days and the remaining half receiving the drug for 180 days. A similar sub-categorization process was utilized for patients/subjects in the Late Treatment Group.

Of the 138 patients/subjects entered into the study, 58 have been dropped from the protocol for reasons beyond our control. These included voluntary withdrawals and, in some instances, our inability to follow these patients after discharge.

Sixty-eight subjects have completed the entire protocol, which includes a 1-year post-injury follow-up examination. At present, the active study population consists of 81 patients who have elected to remain on the protocol and who appear capable of being followed post-discharge and willing to cooperate. Eight patients have completed the drug treatment phase, but still have an annual follow-up examination pending. Five patients are currently completing the drug treatment phase. Follow-up examinations for these patients/subjects will be scheduled subsequent to their completing this phase of the study and being discharged from the center. The study will be terminated and the data analyzed after a minimum of 100 patients have completed the entire protocol■

Dermal Fibrosis in Spinal Cord Injury Patients

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Background—Spinal cord injury (SCI) patients with documented episodes of autonomic hyperreflexia have been observed to develop cutaneous changes characteristic of scleroderma, which is a collagen disease of unknown etiology and pathogenesis. The disorder manifests itself primarily in the cutaneous, vascular, musculoskeletal, gastrointestinal, pulmonary, cardiac, and renal systems. Dense fibrosis may appear in the gastrointestinal tracts, a cystic type of fibrosis may develop in the lungs, renal vessels may show signs of accelerated nephrosclerosis, and fibrosis of the myocardium and respiratory structures may result in cardiopulmonary failure. It is believed that the autonomic nervous system is in some way involved, but supportive evidence is lacking for this condition which is, at present, untreatable. Since the cause of collagen disease is still unknown, it is theorized that these changes in spinal cord injury patients with known autonomic dysfunction may help in understanding the cause, and may suggest appropriate treatment for the collagen diseases in general.

Hypothesis—There is a cause-effect relationship between autonomic nervous system dysfunction and dermal fibrosis in SCI patients.

Methodology—A series of chronic SCI patients with scleroderma-like skin changes have been studied retrospectively. Skin changes have been graded according to a previously developed scale. Blood and urine specimens have been analyzed extensively, and skin biopsies have been collagen-typed via indirect immunofluorescence. Other tests, including comprehensive renal scintigraphy procedures (CRSP) and skin temperature gradient studies, have been performed.

Preliminary Findings—Twenty-one retrospective study group patients/subjects have been entered into the protocol. Complete data are not available on all 21 patients due to (i) loss of some tissue specimens in transit between laboratories; and/or (ii) the inability

of the project team to perform all tests on certain patients.

Generally speaking, blood and urine specimen analyses were not consistently abnormal. Serum alkaline phosphatase abnormalities were identified in four patients/subjects. However, these findings may be attributable to other unrelated metabolic changes in the bony skeleton. Although 8 of 19 patients/subjects were found to have abnormal serum serotonin values, it must be stressed that five of the abnormal values were elevated and three were depressed. The known technical difficulties associated with serum serotonin measurements necessitate revalidation of the finding and considerable prudence in interpretation. Among 14 patients/subjects in whom sedimentation rate measurements were acquired, more (n=9) had abnormal findings than had normal findings (n=5). This was not entirely surprising, since sedimentation rate abnormalities are frequently encountered in the spinal cord injured. Six of 20 patients upon whom renal scans were performed showed some evidence of abnormal findings; however, there was no discernable pattern (viz., similarity) in the nature of the scan data.

The biopsy findings suggest a fairly consistent fibrotic change in collagen in patients with injuries above the sixth thoracic segment who have identifiable clinical changes in skin texture. This confirms our impression that autonomic dysfunction resulting from spinal cord lesions at or above T6 may initiate cellular and/or vascular changes or damage capable of inducing primary or secondary fibroproliferative abnormalities. Completion of this study should increase our understanding of collagen disorders, since many of them have characteristic fibroproliferative changes associated with the pathogenesis of a given disease.

In all, 23 skin biopsies have been obtained: 5 from pilot-study subjects, 16 from patients/subjects comprising the retrospective group; and 2 from "old" control subjects. Twenty of 21 patients/subjects demonstrated pathological changes consistent with dermal fibrosis (viz., scleroderma). The characteristic pathology was not demonstrable in the microscopic evaluation of similar skin biopsies performed in the control subjects (both of whom had sustained spinal cord lesions at or below the level of the sixth thoracic segment). Clinically, pathologic skin changes noted in this population are seen only in patients with spinal cord lesions above the sixth thoracic segment. Indirect immunofluorescence of skin biopsy material with anticollagen antibodies against human interstitial collagen Types I and III showed a pattern of diminished Type III collagen in the upper dermis with accompanying fibroproliferative changes in both the upper and lower dermis. Histochemical studies revealed fairly normal aminergenic activity with decreased cholinesterase activity.

Termination of the project 1 year earlier than planned is based, in part, on the fact that biopsy results have been consistent, and it is doubtful the inclusion of additional subjects will provide any new information■

H Reflex Changes Following Spinal Cord Injury

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

This study was undertaken to determine if H/M ratio, as a measure of central synaptic excitability, varies significantly over time in patients with traumatic spinal cord injury, and if so, during what post-injury period.

Methods—We have serially tested the tibial H reflex bilaterally in six patients (mean age 26.2) with complete, traumatic SCI. Testing began in the first week post-injury in 5 of 6 patients; they were all tested serially through the first 6 months. Testing frequency was approximately 1 or 2 sessions per week during the first month, and 1 session per month thereafter for an average 8.7 testing sessions per patient. None of these patients had febrile illnesses, skin breakdown or other known sources of nociceptive input at the time of testing, that might influence H/M ratio. All six patients had complete cord injuries by clinical examination, in that none had regained any voluntary muscle contractions in the lower extremities during the course of the study. Three patients were started on spasmolytic medications during the course of the study; the other three patients were not. The five patients tested during the first 2 weeks after injury manifested clinically a transition from hypoactive ankle jerk reflexes to normally active or hyperactive reflexes by several months.

Six healthy, age-matched control subjects (mean

age 26.8) were tested twice with a mean interval of 65 days between the first and second sessions and were compared with SCI patients.

We measure maximum amplitude (peak-to-peak) of the H reflexes and of muscle (M) evoked potentials using a grid ruled in millimeters. Maximum H reflex amplitude was divided by amplitude of the maximum M response to yield an H/M ratio, to reduce possible variability caused by changes in recording electrode placement and muscle atrophy. One-way analysis of variance was performed comparing mean H/M ratios over time for SCI patients. Two sample t-tests were then used to compare changes in H/M ratio for SCI patients between three periods after injury (1 month, 2 to 3 months, and 4 to 6 months) and with H/M ratio changes for control subjects. Two sample t-tests of serial changes in H reflex and M response amplitude for SCI patients and age-matched controls were performed over time intervals where H/M ratios changed significantly. All statistical procedures are two-tailed tests.

Results—H/M ratios in control subjects had an overall mean of 0.51 ±.19 (s.d.). For control subjects, mean H/M ratio for session one was .51 ±.15, and for session two, 0.52 ±.23. SCI patients had an overall mean H/M ratio of 0.43 ±.25. These values are not statistically different.

Mean H/M ratio for SCI patients at three time periods after cord injury were: (1) 0.39 ±.18 for the first month, (2) 0.37 ±.22 for the second and third months, and (3) 0.70 ±.11 for the fourth to sixth months. Comparing H/M ratio for SCI patients for the first and second time periods with controls, there was no significant difference; however, for the third period (4-6 months), mean H/M ratio was larger for SCI patients than controls, though this difference was borderline significant. SCI patients not treated with spasmolytic medication were significantly larger than control subjects for this third time period (4-6 months); those treated with spasmolytic medication were not significantly different than controls.

Analyzed separately, the three patients treated with spasmolytic medication still manifested significantly larger mean H/M ratios at 4 to 6 months than at 2 to 3 months. Mean H/M ratios also were larger during the late period for the three patients not on spasmolytic medication, but this difference did not achieve statistical significance. Neither group manifested significant differences between the first and second testing periods.

Discussion—The transition from spinal shock of acute SCI to spasticity of chronic SCI is generally described as a gradual appearance of hyperreflexia. The hyperactive ankle jerk as one clinical manifestation of that spasticity has been said to recover from spinal shock within several weeks to several months in different patients. The SCI patients studied here also showed a transition from depressed tendon reflexes at 1 to 2 weeks post-injury to active tendon reflexes by 6 months.

Temporal Course of H/M Ratio Changes—To assess temporal changes in synaptic excitability of the ankle jerk reflex pathway, maximum H reflexes and M responses were recorded serially and their amplitude ratios calculated.

The five patients tested between 36 hours and 5 days in this study had readily elicitable H reflexes, with significant H/M ratios of .24 to .67. Others also have readily recorded H reflexes between 1 and 4 days after cord injury.

For several weeks tendon reflexes remain depressed or absent, though H reflexes are readily elicited, as we have noted in five cases in the present study. This has been attributed to a persisting fusimotor depression to the muscle spindle, which gradually resolves.

Three to 6 months after SCI, there is a significant increase in H/M ratio and H reflex amplitude, as demonstrated in the present study, suggesting an increase in IA-motoneuron synaptic excitability. This increase was associated with hyperactive ankle jerk reflexes in 4 of 6 patients and was not prevented by the spasmolytic medication, baclofen.

The present study is preliminary. Large fluctuations in H/M ratio were noted during the first month after SCI, though common temporal changes were not present in all patients. Other factors, such as level of injury, corticosteroids, bladder distention, and amount of passive exercise may contribute to the session-to-session variability in SCI patients. Controlling such factors, and performing more frequent serial testing in additional patients, may allow resolution of other common temporal changes.

Introduction of the spasmolytic medication, baclofen, was followed by a decrease in H/M ratio in 2 of 3 patients, though it did not prevent the later increase after 3 months. Baclofen may not be the only explanation for the decrease in H/M ratio at 1 to 2 months, since one non-treated patient showed a decrement over the same interval. Additional studies may be useful to explore the effect of spasmolytic medications on H reflex changes and the evolution of spasticity after spinal cord injury.

Peripheral versus Central Mechanism — The increase in H/M ratio after 3 months could result hypothetically from peripheral muscle atrophy, rather than a central increase in synaptic excitability. Preferential disuse atrophy of muscle fibers belonging to the largest motor-units (i.e., type II atrophy), not participating in the H reflex because of their high threshold, would result in a lower M amplitude but a larger H/M ratio. However, studies have shown that type II, not type I, muscle fibers predominate in chronic SCI patients. Furthermore, we have shown that there is a significant absolute increase in H reflex amplitude contributing to the increase in H/M ratio, but there is not a significant decrement in M response amplitude. Thus, muscle atrophy does not seem to explain this increment in H/M ratio.

These significant increases in H/M ratio and H reflex amplitude, but not M response amplitude, suggest that central synaptic changes underlie at least some of the hyperactivity that develops in phasic stretch reflexes after spinal cord injury. These results do not rule out the possibility that muscle spindle sensitivity increases as well and contributes to the appearance of hyperactive tendon jerk reflexes.

In summary, serial changes in H/M ratio are observed after complete spinal cord injury. A significant increment in H/M ratio is noted after 3 months, largely the result of an increase in H reflex amplitude. Further study of the temporal course of reflex changes after spinal cord injury may yield further understanding of the neurophysiologic mechanisms underlying the appearance of spasticity■

Longitudinal Assessment of Physical Therapy Factors that Affect Quality of Life of Persons with Spinal Cord Injury

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Sponsor: National Institute of Handicapped Research

Objectives — The objectives of this study are:

1. To determine the importance of the patient's compliance in performing weight-shifts in a wheelchair to prevent breakdown of skin in weight-bearing areas of the body;

2. To improve the criteria and procedures for selecting spinal cord injured patients to be braced and trained to become functional ambulators; and

3. To determine the incidence, characteristics, and outcome of pain complaints in patients with severe spinal cord injury.

Reduction in the level of funding has necessitated reduction in the scope of the study. Considering the resources and expertise available, we elected to defer action on Objective 1 (above) and to concentrate on Objectives 2 and 3. As we complete work on the latter, staff effort will be redirected to pursue Objective 1.

The patients being studied are individuals who received severe injuries to the spinal cord resulting in paraplegia or quadriplegia. A total of 70 patients between ages of 20 and 58 years with paraplegia have been studied in pursuing Objective 2. A list of patient attributes, and the equipment and services associated with gait training, was compiled for each patient. Follow-up evaluations 6 months to several years after bracing are being made to assess brace utilization.

It is expected that the results will improve the criteria for identification of those who will remain brace users.

A total of 113 patients between the ages of 11 and 80 years (58 with quadriplegia and 55 with paraplegia) are already being studied in pursuing Objective 3. Information on pain status, method of treatment, and reported success of treatment is gathered on a weekly basis until time of discharge. The results are expected to illustrate trends in the etiology and resolution of pain complaints.

Status to Date — During the past year we have analyzed the results of brace utilization by 70 patients who received bilateral knee-ankle-foot (KAF) orthotic devices and have drafted a report on the findings. Pilot studies have begun with an orthotist, T. Engen, to devise a simplified, lightweight, modular orthotic device for early bracing and gait training. Data concerning the pain complaints made by 113 patients with spinal cord injury during their initial hospitalization for comprehensive rehabilitation have been gathered and categorized. The data have been examined for correlations between population variables, etiology of injury, level and neurological completeness of injury, and location and suspected etiology of pain complaint. Therapeutic procedures that patients have identified as most effective in alleviating individual pain states have been identified. The status of each pain complaint at time of the patient's discharge has been documented.

The plan is to continue analyzing these data to identify relationships that could shed additional light on the mechanism responsible for the state of discomfort, and on mechanisms responsible for allevia-

tion of the discomfort. An indication that a significant number of pain complaints in paralyzed patients may be of the mechanical, low-back variety will be pursued. Collaboration with the orthotist to develop improved methods of early bracing will continue.

Residual Bladder Volume Determination for Spinal Cord Injury Patients

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

The goal of this research is to develop a low-cost, portable, clinically useful method of measuring bladder volume noninvasively. Our approach has been to utilize ultrasonic A-scans plus microprocessor-based numerical algorithms to calculate the bladder volumes. To date, we have completed our laboratory studies on simulated bladders and bladder walls, and have developed a complete laboratory system for measuring bladder volume on human subjects. Volunteer subjects are required to lie on a couch, the bladder area is mechanically scanned with a transducer placed on the skin surface, and the computer automatically calculates the bladder volumes between 45 cc and 225 cc as determined by measuring the voided volume. The average error of the calculated volume was approximately 12 percent using our initial algorithms for detecting the bladder walls and for integrating the distance measurements.

These human laboratory trials are continuing in order to obtain a larger data base for testing possible algorithms. Other significant efforts include the continued development of improved algorithms for more accurate volume calculations, the design of a prototype clinical system for initial testing on patients at the Tucson Veterans Administration Hospital, and the design and testing of the final system.

Development of Analytical and Laboratory Models of the Bladder and Urinary Tract

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The main objectives of this research are:

1. Design and construct a device to be implanted in a dog that will apply pressure to the bladder and force the dog to urinate. It must be possible to activate the device externally without having any part of the device pass through the skin.
2. Develop analytical and laboratory models of the bladder, urethra, and urinary tract.

Implantable Device—A preliminary design has been completed for a device that can squeeze a dog's bladder hard enough to overcome the resting urethral pressure. The device will allow doctors to measure the bladder pressure required to force open the muscular valves in the urethra. The central component consists of a bladder cover and inflatable inserts that can be wrapped around the bladder. A pump placed in the scrotum can be activated externally and moves fluid from a reservoir placed in the belly to the inserts in the cover. The inflated inserts apply pressure to the bladder. In order to relax the bladder after voiding, one can press a release valve in the pump, allowing the fluid to return to the reservoir.

A number of improvements to the current design are being considered. New materials and attachment methods are being investigated, which will allow the device to be installed more quickly and securely. New arrangements for the inflatable inserts, which will apply more uniform pressure, also are being investigated.

Analytical and Physical Models—The objective of this part of the research has been to study the fluid mechanics that occur in the lower urinary tract of a dog—namely, the bladder, the internal sphincter, external sphincter, and the urethra. This objective is being accomplished in two ways. First, a mathematical model is being constructed using the finite element method to model both the flow of urine and the reaction of the tissues to that flow. Second, a physical model is being designed and will be constructed to provide data for comparison to results from the mathematical model.

A preliminary search of the literature has shown that physical modeling has been attempted by var-

ious investigators, and these physical models have been compared and analyzed. Of these models, one presented by Martin and Griffiths in 1976 represents closely the actual mechanics of micturition; however, the circular cell presented by Scott, et al., in 1971, modeled the sphincter quite sufficiently.

A mathematical model of the bladder was presented in 1976 by Beard at the University of Exeter. His results were based upon a theoretical model and were used as a basis for a more accurate mathematical model. Beard considered the longitudinal tension in the urethral wall, and developed various parameters such as "elastic length" and the "spread" of the urethral pressure profile.

It can be concluded from this report that various physical models of the bladder have been developed while very few mathematical models have been completed. Because of this, extra time and effort have been put into the development of the mathematical model, and up to this point in time, that development is being concluded. The bladder neck and the muscles involved in micturition will be modeled using the finite element method. The finite element method is useful in structures and fluid flow because various parameters can be inserted into the elements so as to model that particular element in a more accurate manner, rather than in a sweeping generalization. Furthermore, various points along the bladder wall and within the fluid flow may be checked. This is more convenient than at the boundary conditions. It is the estimate of the investigator that formal studies should be completed by September 1984, and a publication of the results by January 1985■

Neural Mechanisms Underlying Bladder Dysfunction After Spinal Trauma

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An enhanced understanding of the neurophysiology and neuropharmacology of bladder function and of dysfunction following spinal trauma requires the development of an animal model where the animal is unanesthetized, and where many of the neural and muscular events underlying bladder function can be simultaneously measured.

We have produced such a model, in which bladder performance can be continually evaluated through a knowledge of cystometric relationship between bladder volume and pressure. We implant into the bladder a miniature (4 mm diam) transducer to measure pressure. At selected sites on the bladder surface, pairs of small ultrasonic crystals are placed whose distances apart can be measured and used to determine bladder volume. We also can install leads to measure detrusor and pelvic floor muscle electrical activity. The electromyographic leads for these devices are tunnelled under the skin to exit from the back of the animal's neck. So far, we have monitored bladder function before and up to 1 month after instrumentation. This model gives us a tool to monitor bladder function and dysfunction before and after spinal trauma.

The underlying cause for bladder dysfunction after spinal trauma is unknown. Recent evidence suggests that endogenous peptides like enkephalin may play a key role. We hypothesize that a morphine antagonist like naloxone might prove extremely beneficial in helping restore bladder function if applied to the spinal cord just after trauma.

In normal (i.e., uninstrumented and awake) dogs, the bladder volume at which urination began was raised significantly after spinal morphine. This change was reversed by spinal administration of naloxone. Such changes in micturition threshold following spinal morphine injection resembled very closely the changed thresholds that we later saw following spinal transection in these dogs. Further, there was a reduction of micturition thresholds in two of the three acutely transected dogs given spinal naloxone.

While further experimentation is necessary, these preliminary results do highlight a possible role of the endogenous opiates in producing bladder dysfunction after spinal trauma. We are now extending these pharmocological studies to our chronically instrumented animals■

The Bio-Feedback Incontinence-Training Program

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Prostatic enlargement and urologic diseases occur often in the elderly and in the veteran population as the average age of Americans rises. Some veterans suffer from urinary incontinence which can have devastating psychologic and social consequences.

Success in the treatment of urinary and fecal incontinence has been demonstrated by researchers using urodynamic techniques to provide clinical biofeedback training.

Hypothesis—Subjects who receive biofeedback training by means of urodynamic monitoring will demonstrate a significant reduction in urinary incontinence and/or urinary retention.

Purpose—The biofeedback incontinence training program is directed at investigating the usefulness of this new and relatively noninvasive treatment of urinary incontinence for the veteran patient.

Methods of Procedure—The treatment/intervention involves the subject being catherized and monitored by cystometry. Changing bladder pressures and sphincter electromyographic data are recorded on an automatic printout. The subject is positioned to view the readings as they are produced to provide feedback regarding bladder activity. The bladder can be repeatedly inflated with carbon dioxide gas to simulate filling of the bladder. The subject will be provided graphic models of normal micturition patterns to emulate during the biofeedback sessions. The session will last approximately 1 hour and be scheduled every other week. The subjects will undergo a minimum of four sessions, with eight anticipated as a maximum.

Population and Sample—Twenty to 30 veterans, outpatients, or inpatients with a history of urinary incontinence or urinary retention will be the subjects. Excluding criteria will include urinary obstruction and inability to communicate or attend training sessions. Initial screening of subjects will include urologic evaluations and screening for drug use that inhibit or alter normal micturition (phenothiazines, tricyclics, etc.). All subjects will be included in follow-up by phone or by mail. Contact will be made at 30, 60, and 90 days post-termination of treatment.

Special Consultant—Kathryn L. Burgio, Ph.D., Staff Fellow, NIH, NIA, Gerontological Research Center, Baltimore, Maryland■

Effects of Spinal Cord Injury on Drug Metabolism

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Sponsor: National Institute of Handicapped Research

The pharmacokinetics of medications administered to spinal cord injured patients have been widely investigated. There are numerous reports regarding alterations of normal physiological, neurological, and biochemical functions in the spinal cord injured population which raise the possibility that one or more aspects of drug distribution, metabolism, and excretion may be altered in this group. The overall objective of this research is to investigate in a systematic fashion a number of representative drugs commonly used at various times throughout the life of spinal cord injured patients.

The first study will focus on the absorption time profile of two drugs, riboflavin and acetaminophen. For purposes of this study, their critical difference is that riboflavin is absorbed by an active transport process, while acetaminophen is passively absorbed from the gastrointestinal tract. A subsequent study will focus on the disposition of two aminoglycosides in hospitalized spinal cord injured patients for whom antibiotics are indicated because of clinical infections. An indication that the pharmacokinetics of these antibiotic agents differ in these people and able-bodied individuals may be important for providing adequate treatment of infections and for minimizing possible adverse reactions to these drugs by spinal cord injured patients.

Status to Date—This study concerned the absorption time profiles of riboflavin and acetaminophen completed. Absorption of riboflavin was assessed by measuring its urinary excretion in 10 spinal cord injured patients and in six normal subjects. The patients had injuries from the first to the seventh cervical level, and they were between 2 and 15 months duration from the time of their injury. A significant difference between fasted and non-fasted conditions was observed for both spinal cord injured and control subjects in time to reach peak excretion and in percentage of dose recovered. However, the results were identical in the two subject populations.

Absorption of a 650 mg fasting dose of acetaminophen was studied in five spinal cord injured patients by measuring serum concentration using a high pressure liquid chromatographic assay. There was no

significant differences for halflife and area under the curve, but a significant decrease was observed in peak serum concentration. There also was a significant increase in the time to peak as compared to values in the literature.

The results indicate that spinal cord injury does not impair absorption of riboflavin from the gastrointestinal tract. However, as compared with normals, there is a difference in the rate of absorption of acetaminophen, but not in the total amount absorbed.

Studies comparing the disposition of aminoglycosides in spinal cord injured and able-bodied subjects will be conducted next.

Collagen Dysfunction in Quadriplegia

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This two-part project seeks to elucidate the ways in which collagen metabolism is altered in spinal cord injury by determining what the consequences are of such alteration and what causes that alteration. Part 1 is an effort being made to show that administering the drug diphosphonate within 7 days of injury will ameliorate and perhaps prevent heterotopic ossification, urolithiasis, and osteoporosis. Part 2 will develop a method to measure hydroxylysine glycosides in an automated amino acid analyzer to establish the fact that increased concentration of a specific glycoside is an indication of the tissue origin of the collagen being degraded. It is hoped that physicians will be able to use this information to decide what preventive measures are of greatest importance for the individual patient and thus reduce the number of complications following spinal cord injury.

Adrenergic receptors also are being measured by radioligand binding assays. The objective is to show an abnormality in them which in turn may affect enzyme activity within the cell. By doing radioligand assays for the enzyme lysyl hydroxylase and chemical assays of the skin to determine the degree of hydroxylation, an attempt is being made to demonstrate that spinal cord injury causes an alteration in the activity of one of the most important enzymes of the collagen metabolism. If the specific defects in the collagen metabolism of spinal cord injury can be identified, they may be amenable to pharmacological intervention.

Status to Date—On part 1, followup studies on two of the patients admitted to the study in 1982 have been completed. On part 2, glucosylgalactosyl hydroxylysine (glugal Hyl) and galactosylhydroxylysine (gal Hyl) concentrations were determined in 37 weekly urine pools on spinal cord injury patients at various times since injury. In the group between 6 and 60 months after injury, statistically significant differences are seen between glugal Hyl and gal Hyl excretion and skin and bone related problems, respectively.

Insensitive skin morphological studies and hydroxyproline determinations were done in cooperation with the Cullen Eye Institute of Baylor College of Medicine. A manuscript is being prepared for publication. Alpha and beta adrenergic receptors have been measured in 12 additional skin biopsies. The former show a trend towards increasing numbers with increasing time since injury. Work has begun on the skin lysyl hydroxylase activity project.

Neuroaugmentive Procedures for Modification of Abnormal Motor Control in Patients with Spinal Cord Injury

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This project is intended to extend the application of spinal cord stimulation (SCS) for treatment of abnormal motor control to spinal cord injury patients with a degree of preserved volitional control through the use of a broader selection of stimulation sites. We have found indications that better results may be obtained in some cases by considering other stimulation sites, and therefore propose to compare alternate sites of stimulation (specifically lower thoracic and lumbar) with currently used upper thoracic and cervical posterior sites in terms of the effectiveness of SCS for treatment of abnormal motor control in paralyzed patients. Finally, in order to understand the mechanisms of action of SCS in these patients, we shall attempt to find neurophysiological coorelates to the degree of improvement of motor control in spinal cord injury patients. A variety of neurophysiological tests, including multi-channel EMG recordings, evoked potential recordings, and observation of twitches elicited by spinal cord stimulation will be used in this task. Approximately 10 patients per year will be studied.

Status to Date — From a total of 220 referrals of spinal cord injury patients during the year for evaluation or treatment of pain, spasticity, degree of lesion, problems of bladder function, etc., 13 were selected as appropriate candidates for application of SCS, five primarily for pain, and eight primarily for motor disorders. Several of the patients had multiple trials of SCS, both above and below their lesions, allowing a direct comparison of the relative effectiveness.

These procedures have worked well in general, but attempts to place electrodes in the lower thoracic and lumbar regions have suffered from the tendency for the electrodes to move to the anterior side of the cord in this region.

Work on the definition of electrophysiological correlates of the effects of SCS continues, but no definite conclusions have been reached. It has been noted that there may be an antidromic effect of stimulation via sensory fibers in the dorsal columns, which could account for the potential effects of stimulation below the lesion. Muscle twitch studies and evoked potential studies are underway to attempt to elucidate this point. In addition, recording from the epidural space is being vigorously pursued.

Evoked Potentials Study

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Sponsor: American Paralysis Association

The functional integrity of motor pathways following spinal cord injury is generally assessed by means of clinical examination. However, these methods cannot be used to predict the degree of dysfunction, such as occurs during the acute phases of injury. Such knowledge would be extremely valuable, for it would assist in the application of future treatments which might benefit any motor fibers identified as still intact.

Inferences of spinal cord continuity have been previously attempted by recording somatosensory evoked potentials (SEP's). However, this method provides specific information only on intact fibers in the ascending sensory tracts, while frequently the extent of motor and sensory tract damage differs significantly. Previous studies in Dr. Levy's laboratory have demonstrated that discrete, evoked potentials from spinal cord motor neurons may be elicited by direct stimulation of the spinal cord or by transcranial stimulation of the motor cortex.

The current study will evaluate motor neuron evoked potentials studied at various levels of spinal cord injury using a cat model.

Effects of Low-Power Irradiation on Clonus and Spasticity in Spinal Cord Injured Persons

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Sponsor: American Paralysis Association

The deleterious effects of spasticity resulting from spinal cord injury are well documented. Treatments currently utilized to alleviate this condition have met with limited success. Recent studies suggest that low power irradiation of peripheral nerves may markedly reduce both clonus and spasticity in spinal cord injured individuals.

Dr. Walker will examine the effects of laser versus sham irradiation in 20 human SCI patients. Functional recovery following treatment will be estimated by measuring clonus counts, tissue compliance (a measure of spasticity), changes in range of motion, and somatosensory evoked potentials. All subjects will receive a neurological score based on a standard testing protocol.

The results of these tests will be evaluated to determine if treatment is associated with an improvement in neurological performance.

The Effect of Electrical Stimulation of Muscles on the Cardiovascular System

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Sponsor: American Paralysis Association

Dr. Petrofsky has previously demonstrated the ability to stimulate paralyzed muscles with external electrodes so as to rebuild muscle bulk and enable coordinated movements of paralyzed lower limbs. It was observed that such muscle stimulation can cause substantial changes in the cardiovascular system. It can also induce other physiological changes in the subject's thermoregulatory system, where sweating does not occur below the level of injury.

This contract enables the conduct of a series of experiments dealing with cardiac stress during electrically induced bicycling in a thermoregulated environment. Physiologic data will be taken to study

heat adaptation and how well the paralyzed individual can adapt to heat.

In addition, the contract calls for Dr. Petrofsky to document protocols and procedures for establishment and operation of a F.E.S. center, with particular emphasis on all aspects involving patient safety.

C. Spinal Cord Regeneration

Monitoring of Post-Injury Changes

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Sponsor: American Paralysis Association

Ischemia and edema are critical factors influencing the amount of nervous tissue damage that may develop following physical injury. Physiological responses at the cellular level also are initiated by trauma and elicit a series of metabolic responses which appear to further aggravate neuronal integrity. Using a primate model, Dr. Abraham's laboratory will document these vascular and cellular changes at various stages post-injury.

Later studies are anticipated in which several therapeutic regimens, including omental transposition and correction of metabolic abnormalities, will be applied in hopes that such intervention will neutralize the harmful effects normally accompanying spinal cord injury.

Tissue Implant Studies

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Sponsor: American Paralysis Association

Recent studies indicate that tissue implants may restore functions lost after brain injury in rats. Such implants appear to promote the growth of injured axons and may possibly replace the components of damaged axonal circuits.

The current study has been established to determine the effectiveness of tissue implantation techniques for the restoration of function in the injured spinal cord. The growth properties of embryonic tissue implants inserted at various intervals following injury will be examined to test the hypothesis that implants develop better if insertion is delayed following injury (delay paradigm). Additionally, growth promoting and inhibitory factors, previously isolated from central nervous system wound fluids, will be collected, assayed, and evaluated for their usefulness in enhancing the growth of the spinal cord implants and/or other damaged spinal cord tissue.

Collagen Matrix Implant Studies

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Sponsor: American Paralysis Association

Previous studies have attempted to use tissue bridge implants to serve as a matrix for the regeneration of neuronal tissue but have met with limited success. Vascularization of such bridges is generally slow and the bridge itself may form a barrier to regenerating axons.

Dr. de la Torre is studying the regeneration of spinal cord axons using a cell-free collagen matrix of fibers which has previously been shown to support rapid vascularization in host tissues. It is hoped that the loose, cell-free components of the matrix will provide less of a barrier to growth than is usually encountered. The study will also examine the efficacy of in situ drug therapy applied at the site of the tissue bridge implant.

Omentum Transposition Study

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Sponsor: American Paralysis Association

Dr. Goldsmith pioneered the technique of surgical transposition of the omentum to reduce edema (accumulated tissue fluid) and restore circulation following brain trauma. This surgery is now being performed at a number of medical centers worldwide. The application of this treatment to spinal cord injured patients was believed to be of primary value only during the acute phases of injury. Recent data suggest, however, that chronically injured patients also may derive benefits from this procedure. Studies in cats have revealed that neuroelectric activity is partially restored across the traumatized area of the spinal cord following omental transposition, although functional recovery has not been observed.

The current project will study the cat model to

analyze and compare the potential effectiveness of omental transposition used in conjunction with a variety of proposed therapeutic regimens (Naloxone, Diapulse, DMSO) to promote regeneration and functional recovery in cases of chronic injury.

Cortico Spinal Neuron Studies

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Sponsor: American Paralysis Association

The cell bodies of corticospinal tract motor neurons may be dependent on target cell (muscle fiber) input for continued maintenance following spinal cord injury.

This project will test the hypothesis that corticospinal neuron degeneration may be minimized by directly applied administration of a central nervous system derived neurotrophic factor. Dr. Manthorpe's laboratory will attempt to purify one such factor from the bovine cerebral cortex.

Later studies will be aimed at developing a methodology for therapeutic presentation of putative trophic factors to corticospinal cell bodies and/or axon processes using a catheterization infusion system.

The final stage of the study will evaluate the effects of such therapy on the functional recovery of corticospinal neurons following complete spinal cord transection.

Effects of Application of Direct Current on Regeneration of Nerve Cells

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Sponsor: American Paralysis Association

Constant low intensity direct currents (LIDC) have been shown to enhance cellular growth, both within the body and in tissue culture. Prior application of this technique has been limited to the treatment of bone fractures and decubitus ulcers.

The current study will apply this procedure to explore its potential effect on nerve cell regeneration. Initially, the effects of constant LIDC will be studied in sectioned rat sciatic nerve and regeneration will be estimated using electron microscopy and histological techniques.

Later studies will attempt to document the changes induced by LIDC on different neuronal cell types. The technical data obtained from these studies will eventually be used to examine and describe the electrical, neurophysiological, and biochemical changes that occur in spinal cord injured animals from the moment of injury throughout later stages of recovery.

Use of PF in Stimulation of Spinal Cord Neuron Development

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Sponsor: American Paralysis Association

Dr. Turner's study will attempt to characterize the activity of a new central-nervous-system-derived neurotrophic factor (PF) that has been previously shown to stimulate axonal outgrowth in fetal rat retinal explants.

The initial phases of the study will focus on determining the optimum conditions for stimulating spinal cord neuron development with PF in a tissue culture environment. The second phase of the study will examine the stimulatory effects of PF in spinal cord transected rats who have received tissue implants, with animals evaluated for evidence of functional recovery.

D. Independent Living for the Severely Disabled

Conducting a State Policy Study to Help Develop New Options for Independent Living

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Sponsor: National Institute of Handicapped Research

Objectives—This project's goal is to establish an agenda for state executive and legislative initiatives based on concerns of persons with disabilities. In collaboration with the Kansas Advisory Committee for the Employment of the Handicapped (KACEH),

researchers conducted the first statewide survey of concerns of persons with disabilities in Kansas.

Progress—Over 1,400 Kansas citizens with disabilities responded, and dozens of interested parties participated in planning conferences to create the survey, discuss its findings, and plan subsequent actions. Collaborators included state legislators, consumer groups, service providers in ILCs, and rehabilitation centers. The KACEH will address a crucial area of concern: accessibility of public buildings through cooperations from the state attorney general's office and the governor.

Human Concerns of Disabled Persons: Developing New Methods for Addressing Common Community Concerns, and Developing a Human Concerns National Data Base

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Objectives—This project is intended to teach disabled consumers constructive ways to improve their community. A unique self-help method, the Concerns Report Method, has been developed to allow disabled consumers to assess, prioritize, and convey their concerns and ideas for improvement to decision makers. Specific project objectives include providing technical assistance to users of the Concerns Report Method, developing a common data base of concerns, and creating and evaluating new methods for solving identified problems.

Progress—Over 500 disabled citizens have participated in nine different applications of the Concerns Report Method. Reports of major strengths, problems, and ideas for improvement were prepared at the request of ILCs, consumer organizations, and mayors' councils on disabilities in 11 counties in Kansas and Missouri. New projects are underway in Washington, D.C.; Helena, Montana; and, Los Angeles, California.

In the past year, this project also has conducted the only reported research on a specific problem common to many local communities—violations of handicapped parking spaces by nondisabled persons. Experimental research demonstrated the effects of upright posted signs and police crackdowns on violations.

Effects of the Family on Independence

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Sponsor: National Institute of Handicapped Research

Objectives—This research will seek to determine the most crucial elements of intervention to help families plan a successful transition for their adult children who are disabled. The study's aim is to explore the relationship between how much and what kind of future planning families use, and how much stress and satisfaction they experience.

Progress—Over 50 percent of the 60-family sample has been interviewed, and trends suggest high degrees of stress, little available information or family support, and a crucial need for residential options for young, disabled adults. This project has grown out of previous RTC/IL research that has resulted in four book chapters, two chapters in NIHR-sponsored symposia, one training manual, and over 20 workshops and presentations reaching over 1,300 consumers, service providers, and family members.

Utilizing the Concerns of Disabled Consumers to Assess the Impact of Independent Living Programs

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Sponsor: National Institute of Handicapped Research

Objectives—This project is designed to determine the impacts of ILCs on the needs and concerns of disabled citizens. The assessment will be based on repeated statewide use of the Concerns Report Method, as reported in RTC/IL Project R-16 ("Conducting a State Policy Study to Help Develop New Options for Independent Living"). This project also will seek to promote consumer involvement, increase consumer awareness, and provide a new method to determine if overall need is being met.

Progress—The first statewide survey using the Concerns Report Method was completed this year (R-16) and the results of that project will serve as the baseline. This project will conduct two additional surveys and analyze differences between communities with ILCs and those without ILCs.

Systematic Approaches to Consumer Involvement: Training Citizens with Disabilities in Community Leadership

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Sponsor: National Institute of Handicapped Research

Objectives—Although consumer involvement is a hallmark of independent living, ILCs have found it difficult to organize effective and continuing consumer leadership. This project is designed to develop techniques to promote consumer involvement and leadership.

Progress—A unique conceptual framework for consumer involvement has evolved from an extensive review of literature, detailed observations from field studies, and surveys of experts in consumer involvement. As a result, over 200 competencies and strategies involved in consumer leadership have been identified. Three self-help guides for consumers have been developed and disseminated nationally, and procedures are in process for implementing a comprehensive consumer leadership training program.

Training has been provided to over 60 consumers and to 35 students in a university course■

Support for Families: Family Problem Solving

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Sponsor: National Institute of Handicapped Research

Objectives—This research is intended to help families identify a systematic method to solve shared problems related to disability in the family, and to resolve conflicts that impede independence of the disabled member. The study's aim is to develop a problem-solving guide that families can use either independently or with the guidance of an ILC counselor.

Progress—Project staff have collected resources and conducted interviews with a sample of families to identify examples of key issues to be addressed. Materials development is now in progress, and field testing will occur in late summer■

Management Procedures in Attendant Care: A Training Model for Disabled Consumers

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Sponsor: National Institute of Handicapped Research

Objectives—Attendant care is a vital service for many disabled people who live independently, but many lack the skills necessary to train and manage their own care attendant. This project involves developing empirically-based techniques for disabled people to use in training and managing attendants.

Progress—An attendant-care training and management model has been formulated to address two important problems: lack of job specification for attendants, and the consumer's inability to provide objective feedback on attendant's work performance. This model uses performance checklists, which are developed by the consumers, to allow consumers to monitor, evaluate, and provide feedback to caregivers. As a result, the consumer's control is maximized.

A draft of an attendant-care procedures manual has been developed. It includes a directory of generic checklists and instructions for tailoring them to individual needs. The manual is now being used and evaluated by several consumers, and aspects of the model have been disseminated via a research article and a regional training seminar for 45 trainees■

Human Dignity Project

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Sponsor: National Institute of Handicapped Research

Objectives—Despite progress achieved by the independent living movement, disabled persons continue to report unacceptable treatment by some staff of community service organizations. Poor treatment may range from unjustified assumptions about a certain disability's limitations to offensive comments. This project is designed to develop and evaluate a method that consumer organizations can use to help local service providers improve the way they treat disabled consumers.

Progress—Although this is a proposed project, preliminary interviews have been conducted with con-

sumer organizations in three cities, ILC staff, and a number of community service providers. These interviews have identified dimensions of acceptable service in specific service situations. Tentative intervention techniques have been developed to help consumers encourage more acceptable service delivery.

An Analysis and Review of Peer Counseling Provided by ILCs

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Sponsor: National Institute of Handicapped Research

Objectives—According to a national survey conducted by the project, although 58 percent of 120 programs surveyed offer peer counseling, there is no uniform goal or common service technique across ILCs. This project's goal was to prepare a directory to serve as the basis of a network for peer-counseling programs so they can contact each other, avail themselves of existing materials, and consider ways to resolve common problems.

Progress—The survey of ILC peer-counseling programs was completed, and results have been summarized in two research articles submitted for publication. The directory was completed: it covers peer-counseling programs offered by 112 ILCs. More than 350 copies have been disseminated.

Development of an Impact Evaluation Package for Independent Living Centers

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Sponsor: National Institute of Handicapped Research

Objectives—The overall objective is to develop and test an evaluation package that ILCs can use to evaluate their impact on consumers and the community. Because the ILC model is based on a new and novel philosophy, traditional evaluation approaches have not worked.

Progress—A package has been developed and its validity tested. Current work includes testing for reliability, determining error rates for retro-fitting data, and developing effective data presentation methods.

The demand for the package has been very large. As the package is being refined, over 400 manuals were disseminated and 300 professionals and administrators trained to use them. Training has been conducted in three federal regions, and two more regions are scheduled. ILCs in seven states are using part or all of the package. Two articles about the system are being prepared.

Encouraging Private-Sector Initiatives to Improve Community Accessibility

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Sponsor: National Institute of Handicapped Research

Objectives—Architectural barriers still pose major obstacles to independence for people with disabilities. Since few financial incentives exist for private owners of public facilities to remove barriers, strategies must be developed to encourage their voluntary removal. This project is investigating many strategies for reducing barriers, including information prompts, feedback on facility accessibility, and low-cost incentives, such as publicity.

Progress—The first of several intervention studies was begun last fall. Over 350 businesses in Kansas City participated. Results are being used to refine and package the most cost-effective interventions into a set of guidelines for use in other communities. These will describe how to develop accessibility checklists, survey settings, summarize survey information, and complete an accessibility guide. Two research articles are being prepared, and a workshop was presented to 30 participants.

Nongovernmental Funding Alternatives

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Sponsor: National Institute of Handicapped Research

Objectives—Because ILCs cannot rely on continuing federal support, they must have new ways to identify nongovernmental funding sources. This project's goal is to develop ways to help ILCs establish revenue-

based planning procedures, including private foundations, for fund-raising.

Progress—Using results of a 1983 needs assessment survey and working with a local ILC, RTC/IL developed a procedures manual for planning and conducting fund-raising activities. The manual has been widely disseminated, used in workshops by over 30 ILC and rehabilitation program administrators, and used to assist one ILC in creating a private fund-raising foundation.

Promoting Community Support for Independent Living

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Sponsor: National Institute of Handicapped Research

Objectives—This project will seek to increase the general public's understanding of independent living, promote community support for independent living programs, and increase involvement with and acceptance of disabled persons. Model informational packages and self-help guides will be prepared. The impacts of these materials on community awareness and public support for independent living will be evaluated.

Progress—A national survey of ILCs was conducted to obtain information about outreach and community awareness. Survey results indicate the clear need for assistance in promoting community support for independent living and suggest several potentially effective communication techniques, important messages to be communicated, and appropriate audiences to be addressed.

[See also **IV. Spinal Cord Injury, A. General Rehabilitation**, Documenting and Utilizing Programs to Provide Community Adjustment and Independent Living Services for Persons with Spinal Cord Injury]

E. Communication Methods and Systems for the Severely Disabled

Development of a Unified Quantitative Model for Augmentative Communication Systems

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Sponsor: National Institute for Handicapped Research

A conceptual model has been designed to assist in the comparative analysis of all current selection-based augmentative communication techniques. Predictive validity testing using the model is also planned. The model has been fully specified, and a computer program is being written for testing it with actual subjects using augmentative communication techniques. Subsequent extensions of the model will incorporate refinements dealing with the implications of perceptual and motor interaction, and cognitive and language factors. Testing of the model is scheduled for completion by December 1984.

Study of Dominant Single Speech Motor Subsystem Dysfunctions

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The purpose of this project is to quantify motoric abilities for the assessment and treatment of severe motor speech disorders in individuals who are considered candidates for augmentative communication systems. Instrumental measures have been used, including analysis of the lip, jaw, and tongue motor impairments. A jaw fixation prosthesis was utilized, and acoustical, perceptual, and physiological analysis of subjects' speech with and without the prosthesis was conducted. A group of congenital spastic subjects have been compared along the dimensions of fine force and position control in the lips, tongue, jaw, and upper limbs.

The study is scheduled for completion in September 1984. Three publications incorporating the results of the study thus far are currently in press: (i) Barlow

and Abbs: Orofacial fine motor control impairments in congenital spastics: Evidence against spindle-related performance deficits. Neurology, in press; (ii) Barlow and Abbs: Force transducers for the evaluation of labial, lingual, and mandibular function in dysarthria. Journal of Speech and Hearing Research, in press; (iii) DePaul, Abbs, and Barlow: Physiologic and acoustic analyses of the effect of a bite-block prosthesis in a spastic dysarthric. In C. Linebaugh (ed.), Clinical Dysarthria. San Diego: College-Hill Press, in press■

Cooperative and Commercial Facilitation Projects

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The Trace Center conducts cooperative research and development activities with manufacturers and individuals designing software and adaptive devices for handicapped persons. Among those involved in such cooperative tasks during the last year have been: Prentke Romich Company, Shreve, Ohio; Sentient Systems Technology, Pittsburgh, Pennsylvania; Adaptive Communication Systems, Pittsburgh, Pennsylvania; Adaptive Peripherals Company, Seattle, Washington; and Smith-Kettlewell Institute, San Francisco, California.

The activities involved development of a hybrid optical headpointer, conceptual work on a communication acceleration algorithm (Minspeak and Speedkey), an adaptive firmware card for the Apple IIe, an eye-tracking system for use by the severely physically handicapped, and development of an oculoencephalographic system for those with minimal motor control■

Developing International Aids Compatibility Standards

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Sponsor: National Institute of Handicapped Research

Over the last several years, the Trace Center has worked with individuals and groups both in the United States and internationally to develop a standard for interconnection between user-operated switches and electrical communication aids. Two years ago, a Common Interconnection Format for Type 1 interconnections was proposed. Four separate standards now have been developed that cover almost all of the compatibility issues included in the original single standard proposal. The four standards (SET, ISA, SBC, and KEI) have been developed with the assistance of consultants from six countries throughout the field of augmentative communication and computer access. Current work was reported at the RESNA Conference, Ottawa, Canada, June 1984■

Portable Simple Electronic Transducer and Morse Code Decoder to Serial RS232 Converter

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Sponsor: National Institute of Handicapped Research

This project addresses one of the main problems restricting the wider use of portable computers—their limited input capability for switches and joysticks, which are commonly used as input transducers for handicapped individuals. This problem is being addressed through development of a standard input method and standard Morse code keying pattern to decode switch closures and joystick position and convert them into serial information readable by the computer through the serial RS232 port. This is being done in conjunction with development of a portable writing, communication, and computer-access aid under other funding. The project is scheduled for completion by summer 1985■

Information Resources

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Sponsor: National Institute of Handicapped Research

The Trace Center has published an updated version of the International Hardware/Software Registry, containing 70 new entries in addition to 100 original entries that have now been updated. A Telecommunications Resource Book, listing alarm, call, and monitoring systems, as well as telecommunication devices

for the deaf, also is expected to be published in 1984. Cooperation with Tools for Living in the Community and with the Rehabilitation Engineering Society of North America has resulted in publication of a new sourcebook guide on technology for independent living. This sourcebook is now available through the Rehabilitation Engineering Society of North America.

Access to Computer-Based Services for Persons Unable to Use Current Systems Due to Physical Impairments

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Sponsor: National Institute of Handicapped Research

An investigation was undertaken to determine the types of access problems involved in computer-based services such as those being found in libraries. A technical report has been produced (University of Wisconsin, Department of Computer Sciences—Computer Sciences Technical Report #516, October 1983). This report examines the situation at the University of Wisconsin-Madison campus, and analyzes the general computer access problem in libraries as it impacts upon severely handicapped patrons.

Keyboard Emulators

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Sponsor: National Institute of Handicapped Research

Devices taking input from any special communication aid or interface, and translating those signals to the electrical configuration required by a particular computer keyboard, have been designed for the Apple II and IIe, and the IBM PC. They are now commercially available, and work is progressing on development of a multi-computer keyboard emulator that can be reconfigured (by the manufacturer) to work with the IBM PC, the PCjr, the Macintosh, and the Lisa.

CRT-Based Headpointing Input Device

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Sponsor: National Institute of Handicapped Research

Transfer of a long-range optical pointer that is CRT-based (stationary workstation) from the research and development prototype stage to commercial dissemination is in progress.

Comparing Complex Position Averaging Techniques

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Sponsor: National Institute of Handicapped Research

A computer program has been developed for capturing position and movement patterns of individuals using the long-range optical headpointer. The program was tested with 20 subjects, one-third of whom had cerebral palsy, one-third degenerative neuromuscular diseases, and one-third spinal cord injury. Hypotheses tested implementation of a particular hysteresis algorithm, among other things. Data analysis has failed to support the notion that this particular implementation of position averaging is useful across the three subject categories tested, or within any of the three categories. Other findings of the current study include observational data regarding skill acquisition time and mastery of the technique by those with extremely erratic headpointing capability.

Findings of the study were reported at the 1984 Rehabilitation Engineering Society of North America Annual Meeting in Ottawa, Canada, June 17-22.

Adaptation of Standard Tests of Aphasia for Computer-Assisted Administration

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Sponsor: National Institute of Handicapped Research

The Token Test (Derenzi and Vignolo, 1962), the Revised Token Test (McNeil and Prescott, 1978), and the Colored Progressive Matrices (Raven, 1962) are being adapted for computer-assisted administration.

Use of alternative inputs, such as a touch-sensitive screen and a touch-tone telephone interface, are also being explored. Software has been written that provides the necessary graphics capabilities, and initial testing of components with subjects is scheduled. A subsequent project investigating computer strategies for recognizing perseveration and self-correction attempts by aphasic individuals will incorporate these techniques.

A Unique Comprehensive Communication System for Speech-Impaired Persons

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Description—The Comprehensive Communications System for Speech-Impaired Persons evolved from a previous project published as the "Electronic Communicator for Speech-Impaired Persons." The previous unit utilized Morse Code entered by joystick or other two-axis controller and featured user programmable messages, all in a portable microprocessor-based device.

The present system resulted from the field testing of the previous unit in which it was determined that the Morse Code system, while usable, required a definite training time for any speed and was probably not necessary with the advancement of microprocessor technology. The new system, implemented first on the Apple II family computer, uses a joystick to select letters directly. The letters are arranged in a square around the perimeter of the joystick with essential punctuation and a "shift" key for numbers and special functions. The system is easily learned, has capability for user-defined message strings, allows for printing and saving of text to diskette, and presents the letters in a large type font for many who have visual perception involvement along with other motor impairments.

The joystick is used to select each character the user wants to print on the screen. The standard joystick is bounded by a four-sided square. Starting at a predetermined corner of this square, the joystick slides in a clockwise direction along each side. As the joystick moves, its X and Y coordinates change. The program has a table written into it. As the coordinates of the joystick change, the program selects a corresponding character—a letter or number.

That character is displayed in the top left-hand corner of the screen. It is 2 inches high, (on a 12-inch monitor) and may be made larger or smaller as necessary.

When the user slides the joystick to a point where the required character is displayed in the top left corner of the screen, the user presses push button one, PB 1, on the joystick unit. The character is printed on the screen. The joystick is then moved to select the next required character. This mode is called the Writing Mode of the program.

A	B	C	D	E	F	G	H	I
<								J
$								K
HI								L
>								M
Z								N
Y								O
X	W	V	U	T	S	R	Q	P

Note: 1. > is a space key.
2. < is a backspace/correction key.
3. HI is a prewritten work, viz., "HI."
4. · at the center of the square is a period. Other syntax symbols can be added at the particular patient's request.
5. $ is also a prewritten word, of the patient's choice. For the demonstration disk, the patient chose to print the word "FANTASTIC" whenever he selected $.

The present program is available on diskette and requires an Apple II family computer with 64K of memory and a joystick or other two-axis input device. A monitor and disk drive are also required.

Future Plans—Future plans are to reduce the system into a dedicated microprocessor-based device utilizing the Intel 8748 microprocessor, a vacuum fluorescent display, EEPROM memory, and RS-232 serial interface, as well as a special interface to the Apple II family keyboard input. This portable "Joywriter," as it is named, will permit the user to have a comprehensive communication system that is easily learned, may be an independent portable device, and may have a keyboard emulator for the Apple II family of computers.

Efficacy of Remote Delivery of Aphasia Treatment by TEL-Communicology

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Background—There are many travel barriers that inhibit subjects with aphasia from receiving treatment. The remote location of speech-language pathology treatment centers often impedes continued treatment after the acute phase. Because of travel barriers, treatment programs may be based on factors other than the rehabilitative needs of the patient. Considering the large numbers of veterans with aphasia, this comparative study of TEL-Communicology and clinic delivery systems for treatment of aphasic subjects should be of great significance in the areas of service delivery and cost control.

Purpose—The purpose of the project is to compare the efficacy of two methods of delivery of an aphasia treatment program by (i) remote delivery by TEL-Communicology, involving both clinician and computer-assisted delivery, and (ii) face-to-face delivery in the clinic. The comparison of the achievement levels of the subjects in each group is based on:

1. Pre-treatment interim and post-treatment evaluation of patient changes in communication ability, and
2. Statistical analyses of certain health care delivery criteria that measure: (i) availability, (ii) accessibility, (iii) acceptability, and (iv) cost-effectiveness. The long-term objective of the project is to determine (i) if TEL-Communicology is efficacious and cost-effective, and (ii) if it makes quality health care more available and more accessible.

Subject Selection—Subject selection is based on the following criteria:

1. Veteran,
2. Male,
3. Eighty years of age or younger,
4. First left hemisphere thromboembolic cerebral vascular accident,
5. Neurological stability,
6. No other history of brain injury,
7. Between 2 and 52 weeks post-onset at entry,
8. Premorbid ability to read and write English,
9. No more than 12 sessions of language treatment prior to entry,
10. Language severity between 10th and 80th Overall Percentile on the Porce Index of Communicative Ability (PICA),
11. Corrected vision no worse than 20/100 in the better eye,
12. Binaural hearing acuity no worse than 40 dB SRT, unaided, in the better ear,
13. Adequate sensory and motor ability in one upper extremity for pointing, gesturing, and writing,
14. Agreement to participate in the study, and
15. The ability to utilize the telephone and any additional telephonic equipment, or a competent person available to assist in setting up the devices and treatment materials at the subject's residence.

Subjects meeting criteria are assigned to (i) a control group that receives 5 hours of face-to-face treatment, and (ii) an experimental group that receives 5 hours of treatment by telephone. The same stimulus variables are used in both groups. The results of the pre-evaluation, interim evaluation, and post-evaluation determine the rate and amount of improvement in each of the two groups.

Accomplishments—During a 17-month period, 38 aphasic subjects met criteria and entered the study. By May 31, 1984, 15 subjects had completed the 24-week treatment period. The charts of 2,934 neurologically impaired patients were reviewed. Of those, 2,315 patients were rejected because they were not aphasic. Of the patients diagnosed as aphasic, 278 were not accepted because of localization. Ninety-eight potential subjects were rejected because of etiology, and 45 did not meet the criteria of weeks post-onset. The remaining 160 were not accepted because they did not meet the criteria of age, PICA (Porch Index of Communicative Ability), visual acuity, or amount of previous treatment.

Location of Study—The Veterans Administration Medical Centers in New Orleans, Little Rock, Miami, and Birmingham serve as treatment centers. Birmingham VAMC is the project center■

Bliss Symbol-to-Speech Conversion: "Blisstalk"

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Sponsor: The Swedish Board for Technical Development
The Bank of Sweden Tercentenary Foundation
The Swedish Council for Research in the Humanities and Social Sciences
The Swedish Natural Science Research Council
The Swedish Council for Planning and Coordination of Research

"Blisstalk" includes an electronic communication board on which Bliss symbols are selected by a magnet or by scanning: their corresponding linguistic expressions are spoken by a built-in speech synthesizer (or written as text) in the chosen language.

The Bliss symbols themselves were developed by the Austrian, Karl Blitz, in the 1940s. He was deeply impressed by difficulties in communication among people who spoke different languages, or even the same language with different intentions. While in China, Blitz — now calling himself Charles Bliss — was inspired by the Chinese ideographs to develop his own set of characters. He hoped they could be used as the basis of a system of world-wide commonality of expression and understanding. This system was set forth in his nearly 1,000-page work, Semantography, published in 1965.

In 1971, a special education teacher at the Ontario Crippled Children's Centre found a description of Semantography, and obtained a copy for a symbol communication project which had been instituted for nonvocal pre-reading children. The project staff, with consultation from Charles Bliss, developed vocabularies and procedures for use of the symbols which are now called Blissymbols. An institute for the purpose of developing the Bliss system was established in 1975. Located in Toronto, Ontario, Canada, it is called the Blissymbolics Communication Institute.

The use of Blissymbols in Sweden began in 1976 at two regional rehabilitation centers, one in Gothenburg and one in Linköping. In 1977, the Swedish Blissymbolics Resource Center was formed. Interest in Blissymbolics grew rapidly in all of Scandinavia, and the formation of the Nordic Bliss Communication Committee came about a year later, in 1978. According to the Swedish Institute for the Handicapped, there are about 800 children in Sweden who use Blissymbolics in some form; with many of them, it is their primary means of communication.

The groups concerned with speech synthesis and vocal aids for handicapped at the Royal Institute of Technology in Stockholm have, for some years, been interested in implementing a "talking Bliss system." This interest has been encouraged by the Blissymbolics Communication Institute and others concerned with voice-output communication aids. This system was realized for Swedish in early 1981, and has since been developed for English and French. Bliss users interact with a 500-symbol Bliss board which includes a (multi-language) text-to-speech system developed by our speech synthesis group. The system presently contains a formant speech synthesizer implemented on a programmed signal processing chip and a powerful microcomputer. The Bliss-to-speech program transforms the symbol string indicated by the Bliss user to the corresponding well-formed sentence. Bliss-to-text programs have been developed as well, which perform a similar transformation to well-formed written sentences. The user may intermix Bliss symbols and spelled words to produce the spoken or written message.

Linguistic knowledge has been applied in a variety of ways in the realization of this device. An algorithm for producing well-formed sentences employs a lexicon for pronunciation, part-of-speech and special feature information, a grammar to mark clauses and phrases, and morphological rules to produce correct inflectional endings. Words that are spelled using the board's alphabet squares are pronounced by the speech synthesizer according to grapheme-to-phoneme rules or an accompanying "exceptions" lexicon in the chosen language. A set of phonetic rules control the language-dependent sound inventory, adjusting the realization of phonemes in quality, duration, and pitch according to the linguistic context.

Linguistic knowledge has been applied in a variety of ways in the realization of this device. A special phrase structure grammar has been written which marks clauses and phrases, referring to parts-of-speech information in a lexicon containing words corresponding to Bliss symbols. Phrase order is then inspected to determine sentence type. The speech synthesizer incorporates rules for pronunciation and prosody. Bliss-to-speech and Bliss-to-text programs have been developed for Swedish, English, and French languages.

This brief report has been abstracted from a 16-page illustrated paper which appeared in the Speech Transmission Laboratory's Quarterly Progress and Status Report. The paper discusses the development of Blisstalk, its structure, and its modes of operation. The choice of natural language grammar is motivated and differences between this grammar and "Bliss

grammar" explained and exemplified. An Appendix is included which lists possible verb phrase types in English and indicates their availability to Blisstalk users.

[See also **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**, Ocular Controlled Communication and Environmental Control for Severely Disabled Veterans, Interactive Voice Studies and the Design of Command Vocabularies for Voice-Controlled Systems, and Ultrasonic Head Control Unit]

F. Environmental Control Systems for the Severely Disabled

Capuchin Monkeys as Aides for Quadriplegics

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Research has shown that capuchin monkeys have the potential to be as valuable to high-level quadriplegics as guide dogs are to the blind. Current goals include:

1. The standardization of training procedures used in teaching capuchins a basic repertoire of skills. Training procedures for approximately two-thirds of the basic behaviors have been standardized and are described in a training manual. These same behaviors are in the process of being videotaped. Footage will be edited and narrated to produce instructional videotapes.

2. The redesign of equipment that allows the disabled user to direct, reward, and punish his animal helper. The shock/buzz remote control unit used to discipline the monkey has been reduced in size and weight and the harness which holds it, redesigned. Powder and liquid reward dispensers are being replaced by a dispenser that allows a quadriplegic to deliver a variety of food rewards.

3. Redesign and standardization of training equipment. The ease with which monkeys learn specific tasks is partly a function of the design of the training equipment. Equipment continues to undergo modification as improvements in design are discovered.

4. Placement of monkeys. Six quadriplegics are currently using simian aides with an additional two placements expected during the summer of 1984. The number of tame female Cebus apella available to this program is very small. It has limited the number of research placements made. Capuchins placed in the future will probably come from a group now being raised specifically for this project.

5. Exploration of sources of Cebus apella. Young Cebus apella have been obtained from private centers, universities, pharmaceutical laboratories, and zoos. These sources are unpredictable, however, and unlikely to yield more than 5 to 10 monkeys per year. Breeding stock for a Florida-based colony is being sought from Argentina, Brazil, and Peru. This colony should eventually produce 30 to 50 infants per year.

6. Evaluation of all placements. An evaluation of each placement is conducted by project staff. In addition, an independent evaluation of several of the placements will be made within the next year by the Veterans Administration research evaluation unit.

7. An analysis of the type of organization that can train and place simian aides on a larger scale. Such an organization has been described and established. It is Helping Hands: Simian Aides for the Disabled, incorporated in 1982 as a nonprofit organization. Its eventual goal is to train a larger number of simian aides and place them with quadriplegics throughout the United States.

Headwand with Grasp and Release Capabilities

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Sponsor: Wichita Rehabilitation Engineering Center

The objective of this project was to design and fabricate one or more suitable devices that would give the headwand user controllable grasp and release capabilities.

Two devices were designed and fabricated. The first was one that provided for grasping and releasing of objects, with control by puffing and sipping through a plastic tube by the user. The grasp/release mechanism was activated by a sheathed cable which was attached to the diaphragm of a power-brake assist unit that had been salvaged from an automobile. The plastic puff-sip tube was connected to the chamber side of

the diaphragm in the unit and the diaphragm was then moved by the evacuation of air (by sipping), or by pressurizing (by puffing), when the user chose to do so.

The diaphragm in the unit used in this project had a diameter of approximately 9 inches, yielding a surface area of 63 square inches. Since an individual with adequate pulmonary function is capable of sipping and puffing 12 to 14 pounds per square inch, forces in the sheathed cable of the magnitude of 760 pounds are possible (less friction in the cable and mechanism). This was more than adequate to operate the mechanism of the grasp/release function which was developed for this model. Cable forces at the grasping mechanism of 16 to 20 pounds were all that were required to provide for 3 to 4 pounds gripping force, which is adequate to lift most objects that are reasonable in size and weight. The cable did provide some hindrance to the user due to its routing and added weight to the wand itself.

The second design provided for the grasp/release mechanism to be manipulated by a small air cylinder which is mounted at the tip of the wand and is essentially part of the mechanism itself. The wand is lightweight aluminum tubing and supplies air which is pressurized or evacuated from the air cylinder. Supply air pressure is provided by an air tank which can be charged from any supply of air pressure (such as service stations or plant air sources). Very small volumes of air are required for each activation of the mechanism. Therefore, the air tank provides for use of the device for relatively long periods of time between charges.

Control of the mechanism is accomplished by manipulating an electric switch that operates a solenoid air valve. The electric switch is of the microswitch variety and can be easily activated by jaw manipulation, tongue movement, etc., depending on the choice of the user.

A disabled individual was hired as a consultant to help the researchers evaluate the devices. This young man, who has cerebral palsy, has no use of his hands, and has used a headwand for typing, etc., for several years. He was given the first of the two devices (with puff/sip control of the manipulator) in October 1983, with the goal of performing independent daily living tasks for which he had been formerly dependent. No vocational tasks, as such, were attempted using that design. The young man was shown the second device in January 1984, and the evaluation of some simple vocational tasks was carried out in February 1984.

The first tasks attempted by the client in his home using the first device were simple. Such things as picking up pencils, small bolts and nuts, peanuts, etc., and placing these objects at various levels were performed. The first purposeful task that he attempted was to play the game of Monopoly with some friends. He has long enjoyed playing the game, but had to have fellow players move the pieces and toss the dice for him. In his first attempt to do so, he was able to toss the dice one-at-a-time, and then to pick up his playing piece, move it, and place it on the board accordingly.

The second of the two designs was the preferred one to evaluate in a vocational setting. The work station chosen is one that requires the manipulation of small, light objects.

Further research is to be carried out to determine the potential effectiveness of such a device to enhance vocational productivity■

Ocular Controlled Communication and Environmental Control for Severely Disabled Veterans

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

The purpose of this project is to further develop and refine an existing ocular-controlled communication system and to explore the feasibility of using this system for environmental control for severely disabled patients, particularly those with brainstem dysfunction. The Ocular Controller, developed by Denver Research Institute, University of Denver, consists of an infrared-light-emitting diode reflecting off the patient's cornea into a sensing unit that translates eye movements into electronic signals. The signals are averaged and encoded by a microprocessor-based device which is programmable to effect written communication, synthesized speech, and control of a number of switches used for environmental control (EC).

A device was developed, fabricated, and tested with a second patient at the Denver VA Medical Center. Preliminary evaluation showed the patient, a 55-year-old veteran who had sustained a severe brainstem infarct 5 years previously, to have excellent horizontal and fair vertical eye control with minimal nystagmus. There was no motor control of extremities, lips, or tongue. Head control was fair when supported in the semi-recumbent position, but fatigued easily. There

was moderate to severe generalized extensor spasticity. Both verbal intelligence and functional physiological state tested within normal limits, and receptive language and vocabulary were excellent.

For this patient, a three-position Morse code system was used to maximize accuracy of encoding. Modification of the eyeglass-mounted light source and camera produced improved stability and less need for ongoing adjustment of the glasses. However, this continues to be the weakest component of the system, too unstable for prolonged use with this spastic patient in the sitting position, and is still most functionally used by the patient in bed. Modification and reprogramming of the encoding system was successfully accomplished to reduce set-up time to less than 1 minute, enable any caregiver or friend to easily do it, and minimize attendant error.

The communicator was interfaced with a video terminal with memory and dot matrix printer. This allowed the patient to edit and print complex communications. Communication speed with this device averaged 18 to 22 characters per minute. In addition, an orthographic vocal encoder was interfaced with the system. Preliminary experience with this device has been good, although complete evaluation has not yet been done. EC devices were found so far to have little practical application with this patient. In particular, movement of the patient's bed position often caused him to become poorly positioned due to his spasticity and inability to reposition himself. For this reason, it is suspected that independent bed control may not be feasible for patients such as these.

Since the video display and eyeglass component must be precisely positioned and occupy much of the patient's visual field, television tuning was also considered by the patient and treatment team not to be a reasonable goal. Control of room light level has been developed, and is presently being tested. More complicated EC functions, such as telephoning and robotic manipulation, are not considered within the scope of this project.

Further work is planned to include improving the mechanical stability, simplicity, and reliability of the eyeglass system; further simplifying and standardizing the encoder/control system; and exploring the feasibility of simple EC functions with a third patient. The goal remains of more closely approaching a simple, reliable, inexpensive unit suitable for production and delivery to patients in need of this system■

MicroDEC II—Environmental Control System for Computer Access Aid

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The MicroDEC II assistive device was designed to provide a person who has a severe physical disability with control over electrical devices within the living or working environment and the equivalent of keyboard access to an Apple II+ or Apple IIe computer.

Developed as an upgrade and extension of the commercially available MicroDEC environmental control system, the MicroDEC II retains all of the original unit's device control features. Through a two-switch scan-and-select technique, the user can control power to lamps and electrical appliances, and with optional interfaces can control a call alarm, electric bed, and television. The MicroDEC II, like the original MicroDEC, also provides the user with complete control of a standard handset or a speaker telephone. Phone calls can be received or placed, and up to six phone numbers can be programmed by the user and dialed automatically.

In the computer access mode, the MicroDEC II presents the user with appropriate selection groups on an auxiliary alphanumeric display. Characters, words, and commands selected by the user are transferred to the Apple computer through an interface board and appear to the Apple, electrically and logically, as if they had been typed at the keyboard. This arrangement, referred to as keyboard emulation, gives the MicroDEC II user access to any standard off-the-shelf software written for keyboard input.

Beyond simple emulation of the Apple II+ or Apple IIe keyboards, the MicroDEC II enhances text entry for word processing by arranging letters and words within the displayed groups according to their statistical probability of selection. Thus, more likely letters or words require fewer actions to select than less likely items. The MicroDEC II's word resource includes a core group of the 500 most frequently used words and a learning element of approximately 150 words that dynamically reflect the user's topical word usage.

The development phase of the MicroDEC II project has been completed. Our laboratory is now working with a manufacturer to transfer this device to the commercial sector■

Wheelchair Control and Robot Arm/Work Table System for High Spinal Cord Injured Persons

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The objective of the project during this period (June 1983 through May 1984) has been improvement in performance, versatility, and reliability of the Robot Arm/Work Table System (RA/WT) to enable eventual selection of a functionally optimal design as a model for a commercial or production prototype. Prior to this period it was proposed that 2 RA/WT units be rotated between the Spinal Cord Injury Services of the Richmond and Cleveland VA Medical Centers (for clinical evaluation by quadriplegic volunteers associated with these centers) and the Johns Hopkins University Applied Physics Laboratory (for equipment modifications in response to recommendations by these quadriplegics). Collaborative research proposals were submitted to RERADS by the chiefs of these SCI services to cover the clinical evaluation phases conducted in these VAMCs. This report summarizes the equipment modifications carried out in reponse to recommendations received either before or during the report period from the users at the two participating VAMCs.

Modification of the arrangement of telephone components during the previous period was so favorably received during the current period that no need for further modification is anticipated. A variety of relatively minor modifications of the self-feeding components was carried out. This function is now well received by most users. The general problem of space congestion in front of the user's face was improved both by modification of the telephone and introduction of a puff-operated computer keyer. The Robot Arm can be used to change floppy discs in a personal computer, but its lift and grasp force limits, the extent of wrist rotation, and its precision limits restrict its handling of reading materials to sorting and manipulating only the thinnest magazines and pamphlets. The resolution of these problems could substantially enhance quadriplegic productivity with a personal computer or typewriter. It also could permit or enhance user self-grooming. It is believed that the current design of the Robot Arm will accept modifications intended to satisfy these functional goals.

A new microprocessor, a 6809, was chosen and integrated into the Robot Arm controller to increase operational reliability and flexibility. Software design for the old F-8 microprocessor was translated. A computer board was assembled with the 6809. Single axis capability was verified. To shorten task performance time, work was begun on the multiaxial mode capability to control three axes of motion to allow simultaneous operation in a non-coordinated fashion.

A problem was encountered and a solution found to enable more than one person to use the same RA/WT. Each user requires somewhat different end points of the terminal device about his head. A means of quickly changing the motion-file for each user was achieved by using the disc storage capability of a personal computer. In the absence of a personal computer, a wafer drive was found suitable. This unit fits on the support column of the RA/WT. Each data cartridge can hold motion files for at least ten persons.

To enable respirator-dependent and other quadriplegics with limited head and neck motion to use the RA/WT, a new controller was designed and fabricated that uses the jaw muscles (bite) and tongue for control inputs.

Development and Evaluation of a Robotic Aid for the Severely Disabled Individual

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Problem—Persons with physical disabilities such as quadriplegia and severe arthritis have a greatly reduced capacity for manipulating their environments, a condition often exacerbated by reduced mobility. The importance of access to, and control of, one's environment has long been recognized by disabled people and rehabilitation professionals. To date, the need could be addressed only by human attendants and occasionally by trained animals.

Significance—Unlike special-purpose devices and environment controllers, a robotic aid is a general-purpose tool, capable of manipulating a wide variety of objects and performing useful tasks in a changing and unpredictable environment. As a cost-effective alternative and/or adjunct to personal assistance in certain situations, a successful robotic manipulation aid can be expected to enhance the disabled individu-

al's sense of self-worth, functional independence, and productive capacity.

There is also an economic incentive to put robots to work for the more than 7,000 severely disabled veterans. Their labor-intensive attendant care can exceed $50,000 per year. The total cost of human services in industry averages $17 per hour and is rising — the cost of robots averages $6 per hour and is dropping.

Background — The application of robotics to rehabilitation has few precedents. Over the past two decades, perhaps 10 projects can be identified that relate in some way to this human/technology endeavor. Historically, projects were outgrowths of relatively low technology prosthetics research or were (at the other extreme) efforts to apply the type of large remote manipulators associated with nuclear reactor maintenance.

More recently, industrial robotics and artificial intelligence have been making significant progress in developing utilitarian systems that improve industrial productivity and product quality in a cost-effective manner. While these developments have important implications for rehabilitation, their emphasis is on excluding humans rather than working with them. Telemanipulation, on the other hand, seeks to produce a mechanical extension of a human being, exploiting the operator's full range of perceptual, intellectual, and especially manipulative abilities.

Between the extremes of human involvement in the manipulation process lies interactive robotics, of which rehabilitative robotics is a part. The human, exercising a primarily supervisory role, directs the computer system to perform the desired task. A task is as simple as directing a move left action or as complex as serving a meal. The interactive nature of the process implies that the user has, at all times, complete control of the system.

Hypothesis — Based on our expectations that the development of a single general-purpose manipulation system is a more cogent answer to the manipulation needs of the severely disabled than is the design of a multitude of special-purpose aids, our current work is directed towards testing the following hypotheses:

1. The utility of a robotic aid is primarily dependent on the user being able to interact naturally with a machine that is capable of performing a variety of generic tasks autonomously.
2. Natural human-machine interaction is possible if the interface is managed by intelligent programs.
3. Autonomous machines must be able to sense their environment, make plans, and control their actions.

Approach — The VA/SU Robotic Aid has been the first project to be based on a commercially available human-scale, 6-axis, industrial manipulator, driven by high-level software, using totally digital, multi-microprocessor-based control algorithms.

Status — The Robotic Aid Project embodies a clinical system and a laboratory development system. The design of the clinical system has been stabilized to a degree that allows us to pursue intensive evaluation trials with severely disabled individuals at the Palo Alto VA Medical Center's Spinal Cord Injury Service. Over 90 users have been trained to use the clinical system, of whom more than 20 were quadriplegics. The feedback from this user involvement has driven the development effort and defined specific goals in terms of the most desirable (and feasible) tasks. Actual use has pinpointed areas of needed improvement, including planning and control algorithms, environmental layout, command semantics, command phonetics, and procedures for training new users (an important consideration).■

Design of a Six-Axis Joystick for a Robotic Manipulation Aid

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Problem — The utility of a robotic manipulation aid depends largely on the interface between the user and the machine. "Commanding" a system to perform a task can be done through keyboard entry or spoken commands, but "piloting" the mechanical arm is best accomplished by a joystick-like device or some other control interface that uses the motoric capabilities of the user.

Hypothesis — It is our hypothesis that a general joystick-like device allowing control of the robot arm will significantly enhance the performance of the voice-commanded manipulation aid currently in use. The joystick will take over the true "piloting" functions

while freeing the voice communication for supervisory roles.

Further, it is hypothesized that a design allowing simultaneous control of all six axes of the robot will permit the joystick to be a natural interface device, encouraging pointing in any direction. Such a general pointing capability should be combined with a facility to restrict motion to only one axis at a time, thereby eliminating drift in undesired directions.

Status—Three prototype versions of VIDOF, the six-axis joystick, have been designed.

The VIDOF has undergone a preliminary phase of parameter adjustment for able-bodied users. Qualitative feedback from about 20 users indicates that the device requires a training stage before confidence is attained in making complex, high-speed maneuvers of the arm that VIDOF allows.

Future plans include quantitative performance testing, investigating various operating modes, and comparing the range of robot control devices currently available. Finally, the most important goal is extending the design process for the specific need of evolving robot controllers for the disabled users of the VA robotic aid■

Significance—The first generation VA/Stanford robotic aid for the severely disabled was primarily designed to be a voice-controlled manipulation aid, with the user responsible for all of the decision making. While feasibility of voice-controlled manipulation was demonstrated, a performance plateau was reached due to the inability of the machine to absorb some of the burden of control. Without gripper-based sensors, the robot's performance and application were consciously limited for reasons of safety—primarily for the user, but also for the environment and the robot itself.

Hypothesis—It is postulated that performance of any robotic system can be enhanced by sensory aids. With a robotic system under constant supervision of a user, as is the case for the VA/Stanford robotic manipulation aid, the user is always in complete control of the arm's motions. For safe and fast action, the limiting factor is the bandwidth of the communication channel between user and system. For some operations, neither voice nor joystick control may be adequate, and feedback from sensors to the system and to the user is seen as the only reasonable means of correction or redirection of movement.

Sensor and Gripper Development for the Robotic Aid Project

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Problem—The utility of any robotic system is limited to a great extent by its ability to sense its environment and to adjust to unforeseen situations it encounters. Three primary goals are obstacle avoidance, object recognition, and force or position ranging feedback during piloting maneuvers. These goals can only be achieved through the extensive use of sensors on or near the extremity of the robot arm, the gripper.

Development must thus proceed on three fronts: mechanical design (including gripper mechanisms and transducer technology), electronic interfacing (to preprocess the transduced signals for the main computer), and software algorithms (to make optimal use of the sensor information in the attainment of the goals mentioned above).

Status

A. Gripper Design: a third-generation gripper has been developed which incorporates several major design enhancements: higher frame rigidity, greater gripping force, better transmission, and less mechanical backlash than previous versions.
B. Optical Sensors: more robust, sensitive, and compact optical sensors are being used in the current development system gripper finger pads, permitting more sensors to be used in the same space, and better closed-loop algorithms to be developed.
C. Tactile Sensors: whisker sensors have been developed to the single-unit prototype stage, but have not been implemented on the gripper.
D. Microswitch Sensors: the clinical system gripper has been fitted with microswitch pressure plates on the gripping, forward, and lower touch surfaces for elementary obstacle avoidance and alignment to a surface.
E. Conditioning Electronics and Preprocessor Units: a standardized transducer electronics and preprocessor unit has been developed, allowing any multi-sensor system to be incorporated into the general control scheme with a minimum of spe-

cialized interfacing. Both the six-axis force sensor and the new gripper have been interfaced using this procedure.

F. Algorithm Development: the design of a real-time control framework in the main computer for the second-generation development system is complete. Work is proceeding on interfacing the gripper control processor and the force-wrist processor to the main computer. Algorithms have been written to implement closed-loop control from these sensor sources, and are currently being tested. Projects include hovering, aligning, peg-in-hole insertions, centering-and-grasping, object contour following and identification, and obstacle avoidance techniques.

The above elements will be part of the second generation robotic aid development system, presently in its initial stage of full control implementation. The enhancements mentioned will be the first step to endowing the development system with sensory and manipulation capabilities the first generation robotic aid does not have■

Interactive Voice Studies and the Design of Command Vocabularies for Voice-Controlled Systems

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Problem—The state of the art in voice recognition technology has made it possible to use voice as a viable communications link to computer systems in some situations. One case in which feasibility has been demonstrated is a voice-controlled robotic manipulator system for the severely disabled.

Limiting factors of the human/machine interaction center on human performance given machine characteristics and machine performance given human attributes. Errors can result from the incapability of the recognition unit to distinguish between two words with a high level of confidence. Problems also arise from errors that users make in the use or pronunciation of the allowable commands. There is a need, then, to develop tools to construct command vocabularies so that the phonetic differentiability among all words is high, while semantic and syntactic clarity is retained.

Significance—Speech may be one of their only remaining means of communication for people disabled by high-level spinal-cord injury or neurological disorders. This suggests that voice recognition units are potentially very powerful devices for communication with computer systems. The utility of such devices has been demonstrated in the case of the VA/Stanford Robotic Aid Project.

A key component to successful human/machine integration is the voice command recognition rate. If this rate can be increased from the measured overall 85 percent to the theoretically attainable 99 percent, then acceptance, performance, ease of use, and confidence are expected to rise accordingly.

Background—When the first generation of the robotic aid system was assembled 5 years ago, the state of the art in voice recognition technology centered on the digital coding of time histories of band-pass-filtered speech samples. Templates thus created could be stored economically. The Interstate Electronics VOTERM unit was selected because it was one of the better systems of that generation, and because it had extensive diagnostic features.

The voice recognition system cannot monitor or correct its own misrecognitions. A technique was thus developed to systematically tally them manually in order to establish the user's as well as the VOTERM's performance during actual use of the robotic aid.

A pilot study was conducted using five able-bodied and five quadriplegic users prior to their using the VOTERM as an input device for controlling the robotic aid. Once voice training was completed, most of the users achieved recognition rates of 100 percent. However, when the same vocabulary was used in the context of controlling the robotic aid, frequent recognition errors occurred. It appeared, therefore, that further study was required on variables that affect voice recognition during actual use.

It has been shown that training techniques are crucial to establish user confidence and competence in the operation of a complex system. Special attention, therefore, had to be paid in the development of voice training techniques, concentrating on speech consistency, user attitudes, stress factors, and environmental variables.

Hypothesis—It is postulated that a combination of error tallying, template comparison, and user training will remove the most frustrating sources of error for voice control of the robotic aid. By coordinating these efforts, a set of vocabulary design/modification tools can be constructed. More importantly, the utility of voice as a viable means of controlling advanced assistive devices such as the robotic aid can be assessed.

Approach—The general methodology involved the design and development of quantitative analytical tools as well as the evolution of techniques and procedures based on experience and observation of user interaction with the robot system.

The voice command tallying techniques provide information on the commands a robot user employs during a typical 1 to 2 hour training session. To test prospective command words for compatibility with the existing vocabulary, a computer program (VDELTA) was written to perform template comparisons, indicating differentiability in matrix form. Words too phonetically similar could then be removed from consideration.

Training procedures include specific directives on how to provide the speech quality that the voice recognition unit requires. These guidelines began as the manufacturer's suggestions and evolved to include observations by the trainers on the best techniques and most frequent causes of recognition errors. Factors concerning voice consistency and the emotional content of the spoken commands, i.e., those involving the quality of the interaction between the user and the system, are of prime importance in this context.

Status—The robot command vocabulary currently consists of 58 words, and is in its fourth generation (V-4). The first version V-1 was constructed mainly on the basis of functional capabilities. The subsequent version, V-2, was made to incorporate several new command features. No evaluation methodologies were brought to bear at this stage. The evolution from V-2 to V-3, necessitated by user frustration at the quality of the voice recognition, was guided primarily by observations and suggestions by the trainers. Overall recognition rates, as measured by the tally method, dropped from 84 percent to 80 percent overall, due in part to experimentation with 15 new command words.

The evolution from V-3 to V-4 was guided by our experience with previous versions, utilizing all of the tools and methodologies mentioned in the preceding section. The overall recognition rate increased from 80 percent to 86 percent, with a significant shift to types of errors that less seriously affect performance.

Future plans include special-purpose vocabularies for specific applications and the inclusion of several new functional modes requiring new command words. Based on the success of the previous methods, these changes will be made in a systematic way to optimize user acceptance through careful choice and comparison.

The Study of Manipulator Motion Under Constraint

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Problem—Research in hybrid man-machine manipulation systems has identified the need for automatic trajectory generation of manipulator motions. The principle of such hybrid systems is that an operator always has the option of guiding a manipulator through a motion under manual control. However, if a task is easier to describe to the dedicated assistive computer, which makes these systems possible, than it is for the operator to carry it out manually, the operator may ask for a motion to be completed under computer control.

A number of hybrid man-machine manipulation systems have been built and evaluated (Brooks, Buckley). The device described in Buckley is currently being evaluated in other research at RR&D. While it cannot be disputed that such devices increase the manipulative capabilities of the operator that they serve, the degree of useful computer assistance available from these systems has been minimal. This is due mainly to the high complexity required to describe manipulator motions in sufficient detail for them to be executed under computer control.

If such systems are ever to become more than laboratory curiosities, the burden of making implicit information about motions explicit enough for execution must be shifted from the human operator to the assistive computer of the system. Along with the development of an effective human interface, this is a fundamental problem in this field.

Approach—The primary difficulty in manipulator trajectory generation is that of characterizations of collisions. Given an adequate model of the world in which a manipulator operates, it is very easy to determine on a yes or no basis if a manipulator may be placed in a given position. It is not as easy to numerically characterize the relative badness of two manipulator positions in terms of some performance index. Such a characterization is useful in determining how to modify a manipulator position so as to eliminate possible collisions.

It is therefore sought to develop a strong, mathematically consistent numeric characterization of a manipulator moving among obstacles. Having done this, it is sought to apply previous results in numerical analysis to the computer generation of valid trajectories.

Status—The formulation of the trajectory generation problem as a nonlinear programming problem has been accomplished. This includes the development of a piecewise-differentiable constraint function which characterizes collisions that are valid for the entire problem domain. As far as is known, this work is original.

Algorithms have been developed for efficiently calculating these functions for polyhedral sets. Implementation of these algorithms is near completion.

The investigation of numerical algorithms for computing trajectories that take advantage of this formulation is currently in process■

Evaluation of the Human/Machine/ Environment Triad: An Interactive Model Applied to the Robotics Aid Project

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Problem—There is a critical need for user evaluation of rehabilitation research and development products at the prototype stage. There are no established protocols for prototype evaluation, nor are sufficient resources being allocated to carry out this crucial facet of the development process. The government regulates safety and efficacy of market-ready products through the FDA, but has no standardized protocols for evaluation of prototypic rehabilitation products. An environment to facilitate user and applied health professionals' input at all stages of the development process is needed to assure that the products generated are useful to people with disabilities.

The Office of Technology Assessment's Report, Technology & Handicapped People (1982), concluded that: "Evaluation is—or should be—an ongoing and integral part of the entire lifecycle . . . A coherent, and well-focused program of evaluation is necessary at all levels of technology diffusion and adoption. Such a program does not currently exist in the disability-related technology sector." (OTA, 1982) Research must also be conducted to determine what training procedures should be used to introduce people of all ages to new, sometimes sophisticated, products.

Background—There are often communication gaps when professionals trained in medicine, the social sciences, and engineering attempt to explain their differing approaches to solving a problem. Yet the evaluation of complex interactions between intelligent systems and intelligent beings demands an attempt at synthesizing the jargon, styles, and research methodologies of these various fields. The rapidly expanding technological advances, and their unexplored human/machine complexities require an interdisciplinary synthesis of medical, social scientific, and engineering methodologies in order to properly evaluate this class of sophisticated devices. An underlying premise is that intergenerational interaction will also facilitate the development of higher quality products better suited to the varied needs of all segments of our aging population.

A team composed of individuals from a variety of disciplines has been organized to develop research protocols and a working model for prototype evaluation.

Status—This clinical research has generated over 25 professional presentations over the past 2 years. Abstracts are available in the Robotics Information Package. Over 100 users have been trained to use the robotic aid using the interactive evaluation model (Engelhardt, Leifer, et al, 1983) approach. They range in age from 5 to 72 years and include over 22 high-level spinal cord injury patients. A 200-page manual has been developed and utilized by people of varying levels of formal education, from those without high school degrees to those possessing the Ph.D. Training methods are currently being researched in our locus of control study which hypothesizes that successful use of the robotic aid can be enhanced if training style

is matched to user characteristics. Voice studies are ongoing to better illuminate the research questions related to using voice as a control mechanism for a sophisticated assistive device.

Issues in technology transfer are also being actively examined from the theoretical diffusion of innovation perspective, the health services research perspective, and the manufacturer's production perspective.

Ultrasonic Head Control Unit

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Sponsor: Veterans Administration Rehabilitation Research and Development Service
Paralyzed Veterans of America
Invacare, Solo Products, Jib Ray, and Polaroid, Inc.

Problem—Quadriplegics and others lacking control of upper and lower limbs have a need for improved communication and control of their environment. While many interfaces have been developed for use by severely disabled individuals, none are ideal: some have sanitation problems (pneumatic puff/sip switches), while others may physically intrude upon the user (chin operated joysticks) or may be socially objectionable (head wands). Some technologically advanced approaches have drawbacks of their own: eye control units restrict the user's gaze unduly, while voice control provides inadequate system responsiveness and behavior discrimination. Each is limited in its ability to convey the will of the user to operate the device to which it is attached. Trade-offs are frequently involved in their design and use.

Significance—Successful development of a device that can overcome current interface shortcomings would be of significant value to severely injured individuals who wish to control their mobility or communication in a socially acceptable and aesthetically pleasing manner. Desired characteristics would include operation of a device from a distance without the necessity of mechanical contact, use of a part of the body that will not interfere with sensory input, and easy training and use. Other features, such as modular construction, low cost, the ability to accommodate many users, and self-calibration, would contribute to the appeal of the interface, and thereby stimulate its widespread use.

Background—Several methods have been developed to allow a user to communicate with a device to control it. Demonstrated techniques include magnetic induction coils, light emitter/detector pairs, radio transmission, EMG signal detection, EEG signal detection, eye movement detectors, and light reflectance. While the feasibility of each has been demonstrated, each approach fails one or more of the performance criteria defined above. Inherent in many of these potential solutions is the requirement that the user wear a portion of the interface.

Hypothesis—Ultrasonic distance ranging requires no physical contact with the object of interest. A person would not feel encumbered using a device that incorporates this technology. The investigators hypothesize that an array of distance-ranging sensors can monitor the head position of a severely disabled quadriplegic operator to obtain command and control information for the operation of mobility and communication devices.

Approach—In this project, two Polaroid ultrasonic distance-ranging sensors are employed. They emit inaudible sound waves that propagate through the air until reflected by an object. A portion of the echo signal returns to the transmitting sensor and is detected by the associated electronics. The measured time from transmission to the reception of the echo is proportional to twice the distance between the sensor and the object.

In this rehabilitation application, two separate sensors are directed at the user's head. The two distance ranges, one from each sensor to the head, and the fixed separation of the sensors describe a triangle whose vertices are the two stationary sensors and the user's moving head. A geometric relationship allows the offset from the base line and center line of the two sensors to be calculated. This information is then used to map the user's head position onto a two dimensional control space.

In operation, users of the Ultrasonic Head Control Unit (UHCU) merely tilt their head off the vertical axis in the forward/backward or left/right directions. Their changing head positions produce the same effects as a joystick. Thus, the UHCU can be used to control any device usually controlled by a joystick (wheelchair, communication aid, video game, etc.).

The main advantage of this type of interface is that no mechanical contact between the sensors and user's head is required. Users should not feel confined, as frequently occurs with other interfaces. The use of the remote sensing ability of the UHCU should

result in rehabilitation devices that are socially acceptable and cosmetically pleasing.

Status—UHCU's have been installed on two electric wheelchairs. The first is an E&J Model 3P equipped with a reclining Recaro seat and is in use in France by a quadriplegic woman. The second is mounted on an Invacare Rolls IV with a Solo Products Power Pack and is being evaluated by spinal cord injury patients at the VA facility.

Both units have been operational since June 1983. After a short demonstration and training session, quadriplegic users were transferred into the chair and were able to successfully navigate the chair without a problem. Users state that they preferred the ultrasonic head control to the chin-controlled joystick wheelchairs.

Several other applications of the UHCU are being pursued. Used in conjunction with a robotic arm, the UHCU will provide control of the robot's hand position. The user's head position will be used to control two degress of robotic-arm freedom. Compared to the current voice recognition method, a faster and more interactive manipulation of the hand is anticipated.

In a communications application, the UHCU will monitor the user's head position and control a moving light cursor in an X-Y matrix of letters and words. Selection is then accomplished by pausing on the desired square. A commercial joystick-operated aid has been donated for this work.

A technical manual documenting the work on the UHCU, including background material, electronic schematics, computer program listings, explanations, and illustrations, has been compiled. Its intended purpose is to provide information that would allow a technically knowledgeable and adequately equipped person to construct a UHCU and apply it to the control of devices such as powered wheelchairs. This manual has been made available to interested parties who are considering the UHCU for research or commercialization.

International Texas Industries (Intex), of San Antonio, Texas, has made initial commitments in pursuit of production of a wheelchair controlled by the UHCU. They anticipate the first units will be ready by the end of 1984.

[See also **IV. Spinal Cord Injury, E. Communication Methods and Systems for the Severely Disabled**, Bliss Symbol-to-Speech Conversion "Blisstalk"]

Design of Evaluation of Showers and Bathing Fixtures for Disabled and Elderly Veterans

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

The purpose of this project is to finalize the design of four showering and bathing fixtures designed to meet the needs of disabled and elderly veterans. This is being done by conducting an evaluation of the fixtures as part of the ongoing design process. The evaluation is done with several groups of disabled people. The results will determine the validity of each design in terms of access, usage, and safety. The evaluation will also indicate if design modifications are necessary prior to introduction to consumers.

Evaluation Procedure

Testing of Three Fixtures with Subjects Capable of Transferring from a Wheelchair—Due to space limitations, only three fixtures are able to be tested simultaneously.

A. **Description of the Fixtures**

1. A cushioned shower designed primarily for people who transfer to and from the fixture with or without assistance.
2. A fiberglass shower, with two seats, designed primarily for testing usage by right and left hemiplegics. Other subjects (arthritics, amputees, and paraplegics) also will be tested on this fixture.
3. A fiberglass roll-in shower with seat, designed for people who can transfer.

B. **Subjects and Selection Procedure**—The investigators have selected over 400 former patients of the Atlanta VAMC with conditions of quadriplegia, paraplegia, hemiplegia, amputation, and arthritis to be considered potential subjects. Occupational therapists and the investigators are selecting the subjects from this group of 400 people.

C. **Testing and Videotaping**—Testing evaluation activities are conducted in the outpatient clinic of the Atlanta VAMC. The following procedure is used: The occupational therapist trains the subjects in the proper usage of each fixture, then the subject transfers to the fixture and begins to bathe. During all testing, the occupational therapist supervises the subject's activities to insure safety. The testing is videotaped to allow

future analysis of movements and task accomplishment.

D. **Post-trial Interview**—Following the completion of bathing in each fixture, the occupational therapist administers a post-trial interview. The interview deals with success or failure in transferring and the usage of the fixture, as well as a user appraisal of the fixture. The occupational therapist records both her own observations and those of the subject to avoid inaccurate responses.

Future Activities—After completion of the testing evaluation of the first three fixtures, the investigators will test a two-piece, roll-in shower designed for subjects who cannot transfer from a wheelchair.

Following all testing activities, the investigators plan to analyze the data gathered during the interim evaluation procedure to determine if modifications of the fixtures are necessary. After completion of the redesign and modification, the investigators will undertake another testing/evaluation cycle to insure design adequacy of each fixture. It is anticipated that the Veterans Administration will then undertake a formal evaluation of the fixtures at various locations, prior to their commercialization.

[See also **I. Amputations and Limb Prostheses, C. Upper Limb, I. General**, Long-Term Recording of Voluntary Elicited Nerve Signals and **XIII. Sensory Aids, A. Blindness and Low Vision, 2. Mobility Aids**, SONA/SONA ECS]

G. Wheelchairs, Including Seating and Controls

Wheelchair Research and Development

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Sponsor: National Institute of Handicapped Research

The activities of the Rehabilitation Engineering Center during the past year have centered around wheelchairs and seating for the disabled. The seating aspect of the program is relatively new, and as in wheelchairs, the studies are tailored to develop the background information necessary for the effective design of seating systems on either a custom or production basis. The work is shared with colleagues at the University of Tennessee Rehabilitation Engineering Center in Memphis. Four tasks have been actively pursued: tissue physiology, posture studies, anthropometric data collection, and fitting and measuring techniques. An instrument has been developed for recording the shapes of body support while under load which, together with pressure profile measurements, will provide data for the design of modular support components. At the Memphis center, a study of spinal muscle activity in various sitting positions at rest and during activity is yielding information on appropriate postural support. This, with the anthropometric data on disabled persons and the modular components, will provide the envelope of data for effective seat design.

The wheelchair studies, which began several years ago, are continuing with the generation of basic technical information. Comprehensive experiments and analysis have lead to an understanding of caster flutter and a formula to predict the critical speed based on trial, moment of inertia, and tire profile. Tire studies have shown that the roll-off problem associated with no-flat tires can be overcome by increasing the modulus of elasticity of the inner structure. Although the ride characteristics may be impaired, another study has indicated the effect of using springing on the main wheels, and current experiments compare the characteristics of available spring forks for the caster wheels. The study also is associated with frame stresses that are measured experimentally and calculated with computer analysis. A program compatible with small computers has been developed and made available to industry.

Previous work at the University of Virginia developed performance profiles for powered wheelchairs that indicated rather low efficiencies in the normal operating range. Followup studies on motors and controllers have pinpointed certain problems, and a simple choke coil has been introduced to improve motor efficiency impaired by pulse width modulation controls. Work on an adaptive controller to provide user-friendly operation of a wheelchair is progressing and a battery monitoring system is nearly ready for trial. This microprocessor based device monitors charging and discharging, and with a built-in learning capacity will serve as a fuel gage for the wheelchair user.

An investigation into available and experimental batteries continues and a report has been written to assist the purchaser in choosing a battery. A similar study has assessed battery chargers. For the future, a new NICAD battery with non-sintered plates promises improved power density and much longer life.

In product design, the NASA composite wheelchair has undergone testing and modification and a prototype for evaluation is being readied at this time. A lever drive wheelchair has been built that allows the user to move from forward to neutral to brake to reverse by lateral movement of the lever—a function compatible with the ability of most quadraplegics. This design, which uses a 3 to 1 gear ratio was based on ergometric studies that clearly showed propulsion efficiency could be doubled or tripled by using levers and an appropriate gear ratio. The ergometric laboratory recently has been fitted with a three-dimensional arm position recorder and analyzer. With the torque recording and EMG this will yield previously unavailable data on the biomechanics of wheelchair propulsion.

The Rehabilitation Engineering Center has become increasingly active in wheelchair standards, developing and verifying test procedures for use by ANSI (American National Standards Institute) and ISO (International Organization for Standards). A recent contribution resulting from this work has been a method for determining rolling resistance using three light beams and an accurate timer.

Manual Wheelchair with Anti-Rollback Wheel

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Purpose—This ongoing project involves the further development and commercialization of a novel anti-rollback wheel for manual wheelchairs. The system is transparent to the user; i.e., it is controlled entirely through natural movements in using the wheelchair.

Progress—A patent is pending on the initial and advanced designs of the system. Efforts have continued to commercialize the final designs, and equipment has now been purchased that will permit the Atlanta Veterans Administration Medical Center to produce a limited number of units for testing.

Future Plans—As efforts develop to establish a national center for evaluation and testing, this work can proceed. Until national guidelines have been established and funds made available for evaluation and testing, the final phase cannot be completed.

Alternate Transit Vehicle for the Physically Disabled Person

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Purpose—To design systems and subsystems as an alternate to present powered wheelchairs.

Progress—This project began as a graduate feasibility study examining conceptual designs of a transit vehicle for physically disabled persons. It became apparent that the major obstacle to any conceptual design was the fact that the control electronics did not exist. In addition, semistructured interviews with powered wheelchair users revealed possibilities for improvement in present wheelchair controllers. The logical direction for this project then became to examine the electronics of wheelchair control, with a goal of designing a controller that was flexible enough to serve as a retrofit item for present chairs or that could be incorporated in future conceptual designs.

The first prototype has been constructed and is undergoing initial field testing. The controller is microprocessor-based with optical encoder feedback and is an original design in power processing. As a retrofit item for present powered wheelchairs, it offers several advantages in addition to a projected consumer cost below that of present controllers. One advantage is that costly hardware modifications, which customize the controller to special needs, are not needed because the design is implemented in software instead of hardware. All controller characteristics are set in software and are user/therapist programmable. The controller is silent in operation with no audible relay chatter or motor hum. Closed-loop control provides the classical advantages in addition to a "path memory" feature that allows the chair to automatically back out of a confined area along the same path it entered. A degree of self-diagnostics is presently functional and is presented to the user through an eight-character display. The processing power of the controller remains virtually untapped, with much of the signal processing handled by support devices. This allows the controller to assume additional functions in addition to driving the wheelchair.

Future Plans—With the basic hardware design finalized, future work will be concentrated in software development. This involves addressing the human factor questions of wheelchair control. Control strategies to be examined include logarithmic velocity control, proportional acceleration control, deadband limits, and a variety of digital filtering techniques. Additional self-diagnostics are to be incorporated, including current monitoring on each motor.

One of the most promising features of this controller is that it would solve a substantial and growing problem for powered wheelchair users: the congestion of assistive devices on their chair. Each new aid typically requires special attention to make the device accessible to each individual. The joystick or other interface used to drive the chair can also access a variety of other functions. Future plans include incorporating several devices in this manner, including remote environmental control and other aids through the RS232C interface■

Integrated Wheelchair Technology Tested

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Problem—Wheelchairs traditionally have used a relatively narrow range of potentially applicable technologies. Newer technologies (such as synthetic composite structural materials and digital motor control) used in isolation lead to incremental improvements, but are often limited in their potential effectiveness when used in an otherwise conventional configuration. Other issues, such as styling, have not been previously effectively addressed. Wheelchair manufacturers are unable to commit resources to develop designs significantly different from those already tooled and in production.

Significance—Improvements in the mobility of disabled veterans resulting from the use of more sophisticated power wheelchair configurations can improve their ability to access a variety of indoor and outdoor environments, enhancing their integration in society and the economy. New material technologies can yield improved wheelchair durability and convenience, as well as lowered purchase cost, while more attractive styling can ease social integration.

Background—The RR&D Omnichair project resulted in a proof of concept vehicle that is capable of moving forward and backward, moving directly sideways without turning, turning in place, or any combination of simultaneous motions. This novel mobility device became the object of a variety of industrial design studies by interested professionals and students. A graduate student project group developed a programmable digital controller for the Omnichair at Stanford in 1982. It was desired to integrate the experiential results of this work in a working wheelchair technology testbed.

Approach—It was decided that RR&D would undertake the design and fabrication of a wheelchair technology testbed that would embody a variety of new technologies used to their best advantage. The technologies targeted included synthetic composite materials, power MOSFET electronics, nickel-cadmium batteries, and microprocessor-based digital control electronics. It was further intended that the

resulting design would also represent the state-of-the-art in reliability, ease of manufacture, and ease of owner servicing.

The costs involved in building this device were borne by a combination of Base funds (for chassis and mechanical constructions), Merit Review funds (digital feedback controller and power electronics), and industrial cooperation (seating system, motors, and assorted components). The expertise of a large number of center personnel from all three organizational groups was recruited to assist in programming, physical modeling for design of the composite components, styling conceptualization and housing realization, and team support. The physical vehicle was completed in early June in time for the annual meeting of the Rehabilitation Engineering Society of North America, though it was not operational due to software development problems. The vehicle, nicknamed Alexis by the development team, was functionally complete in August.

Status—Substantial industrial interest was generated by the development and completion of this vehicle, and in September of 1983, a venture capital company (International Texas Industries) signed a licensing agreement with the holder of the omnidirectional drive patent. The Alexis is now in an industrial design phase and is expected to be in production by the end of calendar 1984. Work on the vehicle prototype ceased at RR&D upon consummation of the patent agreement. The technologies and designs developed for the prototype (power electronics, digital controller and proportional-integral feedback algorithms, synthetic composite chassis/suspension) are freely available to any interested parties■

Wheelchair Feedback Controllers

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Problem—Users of electric wheelchairs often have difficulty controlling their mobility device due to its poor response. Most current electric wheelchair controllers operate in an open-loop mode, providing no compensation for disturbances affecting the wheel speeds. Electric wheelchair users frequently encounter situations that cause unwanted variations in both the velocity and the direction of their wheelchair. Traveling on hills and sides of slopes, and maneuvering on carpet and across bumps, are examples of situations that impose a heavy control burden upon the wheelchair user.

Significance—Improvements in the handling of electric wheelchairs both indoors and outdoors will be facilitated by this research. The development of a broad-based digital controller will provide people having minimal muscular control the means of controlling a wheelchair, thereby making wheelchairs useable by a greater portion of the disabled population. It will also enable the new generation of omnidirectional wheelchairs to be practical and controllable. Evaluation of controller performance will provide a more accurate understanding of the ergonometric aspects of wheelchair control and the effectiveness of various control schemes.

Background—Invacare Corp. is marketing an electric wheelchair with feedback control using motor voltage and current information processed by electronic circuitry based on discrete components. A number of research groups are studying microprocessor-based feedback controllers with wheel-velocity sensors. Work has been done at the University of California at Berkeley on the modeling and computer simulation of a conventional electric wheelchair with conventional control system and with a closed-loop controller.

Concurrent with the design of microprocessor-based controllers and control schemes for wheelchairs, the present project seeks to develop good dynamic models of two types of wheelchairs: the three-wheel-drive omnidirectional vehicle developed at the RR&D Center, and the conventional two-wheel-drive power wheelchair.

Hypothesis—A velocity-feedback controller should provide greatly improved response compared to that of an open-loop controller. The questions are (i) what feedback algorithm should be used? (ii) what parameters should be sensed to achieve the desired control? (iii) is a microprocessor the indicated hardware?, and (iv) how can the effectiveness of individual schemes be measured?

Approach—The VA controller project uses the technologies and methodologies of electric motor control, power electronics, digital control theory, ergonometrics, and system evaluation. The project's specific objectives include: (i) design and development of solid-state power bridges suitable for providing pow-

er from wheelchair batteries to DC motors; (ii) design and development of microprocessor-based controller hardware suitable for an omnidirectional wheelchair; (iii) development of control software for an omnidirectional wheelchair; (iv) implementation of power bridges, controller hardware, and controller software on Alexis, an omnidirectional wheelchair; (v) design and development of a microprocessor-based controller module suitable for use on the spectrum of conventional two-wheel-drive electric wheelchairs; (vi) development of controller software for conventional wheelchairs; (vii) packaging of power bridges and controller hardware into a stand-alone module; (viii) implementation of power bridge/controller module on a conventional electric wheelchair; (ix) evaluation of controller performance for omnidirectional and conventional wheelchair applications; and (x) documentation of results in form suitable for manufacturers' use.

Status (in commercial development)—The controller development for the omnidirectional wheelchair has been completed; the design is serving as the basis of a controller now being developed commercially. Evaluation of the Alexis controller will proceed as prototypes become available. Current emphasis is upon determining the relevancy of various factors to wheelchair control, as well as the development of the controller for conventional electric wheelchairs. Evaluation of this controller will follow soon after its implementation■

Images Project

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Problem

A. Externally Powered Mobility—While general specifications for a personal vehicle can be stated, there has been little effort to develop the tools needed for a systematic research, development, and evaluation program. This problem is encountered when one attempts to increase user access to existing powered wheelchairs and/or improve wheelchair performance for current users.

1. Who can use existing powered wheelchairs safely?
2. Under what operating circumstances can they be expected to perform satisfactorily?
3. What are the key features of existing wheelchairs which facilitate or limit their effectiveness?
4. What percent of the potential users elect to remain immobile because they don't like existing wheelchairs?
5. What are the key features needed to make powered wheelchairs more accessible?

B. Low Vision—While general specifications for a personal vehicle can be stated, there is no equivalent knowledge base for research and development related to low vision aids. This is particularly true for applications involving mobility and orientation. And, while the situation is better with respect to reading aids, there is profound need for new tools to study low-vision phenomena, and a systematic development program to utilize the knowledge gained. The performance of the rehabilitation community in bringing new technology to bear on this class of problems is particularly notable as the field of robotics moves towards the realization of general purpose machine vision systems—while we waste the chance to help low-vision individuals effectively use the vision they already have.

1. What does the individual with macular degeneration, retinitis pigmentosa, or a cataract really see?
2. How could the visual world best be "enhanced" for presentation to a specific individual's retina?
3. What training procedure will maximize performance while taking individual preference into account? and
4. What are the critical performance specifications for the next generation of diagnostic, training, mobility, and reading aids?

Significance—It is uniquely possible in simulation studies to simultaneously measure performance and preference. This unique capability facilitates the maintenance of a balanced R&D program. Typically, technical members of the development team are biased in their consideration of the technical aspects of system performance. Medical members of the team are biased to evaluate the physiological performance of the patient. Only the patient/user is biased in favor of his/her own preference. And, it is preference which determines what devices will and will not be used after the patient goes home.

Hypothesis—It is hypothesized that simulation science and technology should play a central role in rehabilitation. There are three key levels of implementation:

1. General purpose high performance simulation is needed to define the limits of human and machine performance and to define the necessary and sufficient conditions for solving specific problems. Such systems are powerful, complex, and require highly skilled operators.

2. Task-specific simulation is needed for clinical diagnostics, treatment, and professional training. Moderate operator skill is required. The specifications for such systems may be derived from basic studies.

3. Personal (single user) simulators are needed for extended therapy and performance maintenance. They would be used at home, user owned and user operated. Their specification would be derived from basic studies and confirmed in the clinical setting.

Approach—Using the simulator gift from Singer Link Co., the following three-part effort will be undertaken:

1. A graphic data base will be constructed and developed that can be used for both low vision and wheelchair studies. A single setting, that of the Stanford Shopping Center, has been chosen for both studies.

2. A pilot study will be performed to assess the feasibility of using Digital Image Generator (DIG) technology in the study of wheelchair mobility. The dynamic equations of motion for an existing wheelchair have already been derived in the course of our ongoing work on wheelchair controls. With minor parametric changes, our initial wheelchair pilot study can be based on existing software. The driving environment will be that of the Stanford Shopping Center data base indicated above.

3. A pilot study will be performed to assess the feasibility of using DIG technology to study the impact of low vision perception on mobility. It is believed that this study can (for now) best be done in the context of wheelchair use by persons with low vision.

Status—A high-resolution, real-time, color Digital Image Generator has been donated to Stanford University and is on permanent loan to the VA. A preliminary version of the Stanford Shopping Center data base has been developed and a pilot demonstration videotape has been produced which demonstrates the capability of our system■

Seating System for Body Support and Prevention of Tissue Trauma

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The purpose of this project is to investigate the factors that influence the development of pressure sores and postural deformities in the seated spinal cord injured individual and to develop seating system components that help to reduce the incidence of such problems. A universal contoured foam wheelchair cushion (VASIO-PARA) has been developed and clinically evaluated with 81 subjects. The cushion was found to be successful in reducing the pressure applied to the tissues of the buttocks to levels well tolerated by 79 percent of the subjects. The cushion was transferred to commercial production after incorporating design improvements based upon the findings from the clinical study.

Present efforts on the project are directed toward developing a better understanding of the interrelationships between cushion materials, design geometry, and subject's body build and the resulting pressure distribution over the sitting surface. Investigations also are being conducted on how variations in sitting posture alter the pressure distribution and pelvic orientation and how the cushion and trunk support components can be designed to accommodate and/or promote an optimal sitting posture.

To date, over 200 patients have been tested on the commercial version of the cushion and several design variations. The commercial cushion incorporates a waterproof coating that is washable to improve hygiene and help reduce bacterial growth. In order to determine if the coating alters the pressure distribution characteristics of the cushion, subjects were tested on a cushion with the coating and on one without it. No statistically significant difference was found between the two cushions.

Inserts of firmer foam are imbedded in the cushion beneath the trochanters in order to increase weight bearing in this area and decrease the load applied to the ischial tuberosities. The importance of the spacing between the inserts was investigated by comparing subjects on two cushions, one with a 7 inch spacing and one with an 8 inch spacing. The mean ischial pressure (mean ± standard deviation) on the right side was 85 ±27 mmHg for the 7 inch cushion and 66 ±16 mmHg for the 8 inch cushion.

Similar results were seen beneath the left ischium, while no significant change was recorded at the trochanters. The manufacturer has been informed of these findings. Design variations for the inserts are currently being tested to develop an insert that distributes the pressure more evenly over the trochanters.

Preliminary work has been initiated to investigate the response of skin blood flow under conditions of applied mechanical loading. A laser doppler capillary perfusion monitor is being used to noninvasively monitor the skin blood flow. This may eventually lead to criteria for identifying patients at risk for decubitus ulceration■

Modular Seating for Children

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Sponsor: Scottish Home and Health Department

A survey carried out by Dundee Limb Fitting Centre to determine the seating problems of the disabled population in Dundee found that there was a particularly important group of children with moderate seating problems who do not have adequate seating. The principal characteristic of this group of children is inadequate head and/or trunk control. Their prevalence was estimated to be 250 per million of the total population. Cerebral palsy is the main diagnosis while spina bifida and a variety of myopathies contribute smaller proportions. It is considered that a suitable seating system would help these children to develop head and trunk control and encourage a symmetrical seating posture.

A number of commercially available seating systems partially satisfy this requirement, and a number of these currently are being fitted to evaluate their effectiveness. It is anticipated that a modular approach will be employed in the development of a new system. A series of seat and back modules will be designed to accommodate the large age and size range of the children. The modules will be located in a standardized metal framework by a series of clamps that allow some adjustment. The complete chair will be designed either as freestanding or to fit into a standard-type wheelchair.

The functional performance of the chair will be assessed during clinical trials. These will involve controlled subjective assessment by staff, attendants, and children using the chairs.

The final stages of the project have as their goal ensuring that the system becomes generally available as a commercial product■

Modular Seating for the Elderly

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Sponsor: Scottish Home and Health Department

A survey of the numbers and types of seating problems was carried out some years ago in Dundee District. The elderly were found to account for more than 75 percent of those identified as having inadequate seating or requiring special seating. The severity of problems among the elderly ranged from minor problems (such as some difficulty rising) to extremely severe problems such as skeletal deformity, pain, and no postural stability. The deficiencies in current seating fell into the following general categories:

1. Physical size—the dimensions of the chair do not match those of the person using it.
2. Postural support—the chair does not give support to compensate for loss of postural stability of the user.
3. Discomfort—this is most commonly a result of the deficiencies in 1. and 2.
4. Transferring—the height of the chair, position of the armrests, etc., are not the optimum to assist transfer to and from the chair.
5. Mobility—attendant-propelled hospital chairs are generally hard to push and difficult to steer.

A modular system, with a variety of seating components available to mount in an adjustable framework, appeared to offer the best opportunity of catering for the range of physical dimensions. A range of modules have now been developed that may be assembled together to make a chair to suit the requirements of the individual patient. Four sizes each of seat and backrest modules have been constructed, with one style of headrest and one style of armrest at present. The system was evaluated initially with the modules mounted in a static frame. Each chair was adjusted to suit the individual using it. This showed that great improvement could be obtained in fit, comfort, and postural stability over the furniture available in the hospital in which the evaluation was conducted. Ambulant patients generally found that transferring was improved as well because the armrests protruding beyond the seat front were useful points of support.

A further evaluation with chairs preset to give four sizes in a standard configuration suggests that between 70 percent and 80 percent of the target population could be accommodated in a small range of chair sizes with adjustments reduced to height, headrest position, and, possibly, armrest position. The armrest design is important to facilitating transfer to and from the chair and also is being investigated at Dundee Limb Fitting Centre. When the mechanics of rising from a chair are more fully understood, it is hoped that it will be possible to devise a simple system of prescribing the optimum armrest characteristics for an individual with difficulties in transferring.

A number of mobile chairs now also have been produced, and mobility is immediately improved compared with most hospital chairs by using larger wheels. However, the optimum wheel size, tire construction, and push handle and wheel positions are still to be finalized.

H. Personal Licensed Vehicles

Building a Data Base for Standards for Personal Licensed Vehicles

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Sponsor: National Institute of Handicapped Research

The Rehabilitation Engineering Center for Personal Licensed Vehicles (PLV) was established at Louisiana Tech University in September 1983. It will continue, and expand, research and development already in progress at the University's Department of Biomedical Engineering.

Data gathered at this facility will provide the basis for further development of the center's driving simulators as (i) a testbed for evaluating the adequacy of various control devices relevant to severely disabled clients; (ii) a training simulator with expanded tracking, braking, and acceleration tasks, randomly generated on the computer screen; (iii) further expansion of the growing data base of disabled drivers; performances from referred driver assessment and training clients (via the State Division of Vocational Rehabilitation), with (iv) statistical correlations between simulator performance and in-vehicle performance during training.

Mathematical modeling of the driver's in-vehicle environment will analyze critical demands such as range-of-motion and strength and control variables applied to a specific vehicle such as the Scott Van. Quantitative assessments of a client's capabilities, using the Available Motions Inventory (AMI) approach, will be computer-linked to allow graphic display and analysis.

Psychological and cognitive functioning will be assessed using computer-based testing procedures (developed from validated tests such as Wais Picture Completion Test). Current microcomputer-based assessment will be applied and expanded to measure client needs related to secondary control devices.

A system analysis of available devices will develop standards for the marketing and application of assistive driving devices. Guidelines will be developed for the integration of the system's components into a workable, reliable solution to the client's driving needs.

Information dissemination of project results and outcomes will include videotaped programs, slide presentations, journal and textbook publications, technical-scientific conferences, newsletters, Tech Briefs, and satellite-linked training.

An extended van will be converted to a mobile testing and driver training vehicle. The van will include a driving simulator; testing equipment—to measure vision, hearing, range of motion, and strength of the disabled driver; and, a small computer for processing test data. A local hook-up will supply power.

The van will travel to vocational rehabilitation centers, other rehabilitation facilities, and possible testing sites within a 500 mile radius of the center. This area includes Shreveport, Baton Rouge, New Orleans, Louisiana; Houston, Dallas, Texas; Little Rock, Arkansas; Jackson, Mississippi, Birmingham and Mobile, Alabama; and, Memphis, Tennessee.

A Driving Simulator for the Physically Handicapped Person

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Purpose—The Handicapped Driver Simulator is a system designed to facilitate therapeutic evaluation of the hardware to be retrofitted to a handicapped driver's vehicle. It consists of a full-scale mock-up of the necessary portion of a van interior, including

steering wheel, dashboard, seat, and other items necessary for driving. In front of this dashboard is a large screen monitor, driven by a modified Apple IIe microcomputer on which the simulation takes place. This system is designed to allow easy changing of hardware configurations and thus allow an individual to be evaluated for many different retrofit systems.

Progress Report—In September 1983, the initial design for the Handicapped Driver Simulator was completed. A summary report was written and the engineering drawings were prepared. This led to the ordering of the components that were unobtainable locally. Bolts, nuts, screws, etc., were not ordered at the time because of their widespread availability. Space for the construction of the project was arranged, but no construction has started due to shipping delays in the arrival of the components.

The software for this system is still under development. The electronic modifications for the driving microcomputer have not yet arrived, but are expected by the middle of June. These consist of a Motorola 68000 coprocessor board and a Supersprite board. The coprocessor will greatly increase the computational speed of the Apple by virtue of its 32-bit MPU. The Supersprite board will give the Apple the ability to display up to 32 Movable Object Blocks (MOBs) on the large screen monitor at one time. This should easily facilitate real-time driving simulation on the system.

Future Plans—The system will be constructed in the mechanics lab at the Atlanta VAMC. Materials for the frame have arrived, and the remainder of the parts are expected within several weeks.

There also are other uses for this system. Not only can it be used for evaluation and to familiarize drivers with the equipment to be installed in their vehicle, but in the future it may assist in the training of handicapped drivers. The system also may be used as a testbed for development of new handicapped driving aids■

I. Functional Electrical Stimulation

1. General

Development and Evaluation of Safe Methods of Intracortical and Peripheral Nerve Stimulation

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Functional electrical stimulation (FES) is a means of replacement or augmentation of lost or impaired neural activity. Important considerations in potential therapeutic applications of FES are the design of biocompatible electrodes and the selection of stimulus parameters that will safely and effectively activate target neuronal populations or peripheral nerves.

Work in this laboratory has included the design, fabrication, and in vivo evaluation of surface and penetrating electrodes for activation of cortical neurons and of various types of electrodes for stimulation of peripheral nerves. During the past 3 years this laboratory has developed stimulating intracortical microelectrodes (STIM) for activation of discrete populations of neurons of the cat's sensorimotor cortex. The STIM are fabricated from Pt30%Ir, or pure iridium, and implanted in the precruciate gyrus of adult cats under general anesthesia. The electrodes have smooth, beveled tips with geometric surface areas of approximately $20 \times 10^{-6} cm^2$. Three weeks after implantation of an array of three STIM electrodes, a recording electrode is inserted stereotaxically into the ipsilateral medullary pyramidal tract to monitor the compound action potential (CAP) reflecting the neural activity evoked by the STIM during continuous stimulation for periods of from 24 to 160 hours. The stimulations are conducted using charge balanced, symmetrical, constant current, cathodic-first pulse pairs, 200 μsec/phase in duration at 20 pulses per second, at charge densities ranging from 150 to 3200 $\mu C/cm^2 \cdot ph$.

A computerized data acquisition and control system for conducting stimulation and recording procedures has been developed for freely moving animals. Early components of the CAP remain quite stable during continuous stimulation at 20 to 40 μamp,

although some diminution is observed over 24 hours. Late (transsynaptic) components of the CAP undergo greater attenuation. However, cortical stimulation at 320 μamp (3200 $\mu C/cm^2 \cdot ph$) for 24 hours produced profound elevation of the threshold of early and late components of the CAP that is not reserved 7 days poststimulation. This is consistent with histological findings of neuronal damage and loss within tissue surrounding these electrodes. However, neurons adjacent to these electrodes were activated by charge densities as low as 100 $\mu C/cm^2 \cdot ph$ as indicated by CAP recordings.

In vivo dissolution of surface platinum and STIM Pt30%Ir electrodes has been observed. With surface (subdural) platinum disc electrodes, erosion of platinum occurred at charge densities exceeding 20 $\mu C/cm^2$. At 100 $\mu C/cm^2$, 50-339 ng Pt/site was observed after 9 hours of stimulation. The rate of platinum dissolution gradually decreased during stimulation in vivo, probably due to protein inhibition of the dissolution process, which has been shown to occur in vitro. Pt30%Ir STIM electrodes also undergo dissolution of the uninsulated tip when pulsed in vivo. Scanning electron microscopy observations indicated erosion of the tips after pulsing for 24 hours at charge densities of 200 to 3200 $\mu C/cm^2 \cdot ph$ or 1 week at 200 $\mu C/cm^2 \cdot ph$. However, STIM electrodes fabricated with pure iridium, and whose uninsulated surface is activated by the deposition of a high valence oxide film, appear superior to STIM fabricated from Pt-Ir alloy; the activated surface does not undergo dissolution nor cause neural damage when pulsed with geometric charge densities up to 3200 $\mu C/cm^2 \cdot ph$.

We also have begun assessment of metabolic changes in the neuronal micro-environment with prolonged electrical stimulation. Ion-selective microelectrodes were used to monitor changes in the concentration of potassium $[K^+]_0$ and calcium $[Ca^{2+}]_0$ in the extracellular compartment of the cerebral cortex of anesthetized cats during as long as 4 hours of continuous stimulation of the cortical surface. At stimulus charge densities shown to induce only minimal localized histologic changes (20 $\mu C/cm^2 \cdot ph$ at 50 pulses per second), $[K^+]_0$ at a depth of about 750 μm underwent only a transient increase at the beginning of stimulation, followed by a rapid return to the prestimulus concentration, while $[Ca^{2+}]_0$ was unaffected. At a higher charge density (100 $\mu C/cm^2 \cdot ph$ at 20 pulses per second) there was a rapid transient increase in $[K^+]_0$, followed by a more gradual return to a plateau about 1 mM above the prestimulus value. $[Ca^{2+}]_0$ usually underwent an initial increase followed by a slow decrease to a plateau value above 0.5 mM. At a charge density of 100 $\mu C/cm^2 \cdot ph$ and 50 pulses per second (shown in histological studies to induce significant neural damage), $[Ca^{2+}]_0$ slowly decreased to near or below 0.5 mM in the middle layers of the cortex. After 30 to 40 minutes of stimulation, $[K^+]_0$ underwent episodic fluctuations about a plateau value 0.5 to 1 mM above the prestimulus concentration. Simultaneous recordings of the compound action potential in the ipsilateral pyramidal tract indicated that these fluctuations were due to local changes in the excitability of intracortical circuitry conditioned by the intense stimulation. The results have implications for the possible interrelation of the changes in extracellular ionic concentration and the early stages of stimulation-induced neural damage.

Histologic evaluations carried out on the same animals in which the ion-selective electrode measurements were made indicated a positive correlation of neural damage with both charge density and total charge. With electrical stimulation of low charge density (20 $\mu C/cm^2 \cdot ph$, 50 pulses per second) a transient increase in $[K^+]_0$ was observed with no histologically demonstrable neural damage. The most intense electrical stimulation (100 $\mu C/cm^2 \cdot ph$, 50 pulses per second) resulted in a tonic increase and episodic fluctuations of $[K^+]_0$ and a marked decrease in $[Ca^{2+}]_0$—accompanied by moderate neural damage in the form of shrunken neurons, widespread extracellular edema, and swollen axons and dendrites.

These findings indicate at least a rough correlation between the threshold of neural damage due to electrical stimulation and the capacity of the brain's homeostatic mechanisms to maintain the extracellular concentration of K^+ and Ca^{++} at their prestimulus values.

Studies on stimulation of peripheral nerve also have been conducted. Histological evaluations of dog sacral nerves were carried out following stimulation to produce electromicturition. Two cuff-type electrodes and one spiral-type electrode were implanted chronically. A marked buildup of connective tissue around the nerve and filling the lumen of the array of both types of cuff electrodes was noted 1 to 6 months after implantation. The nerves were extruded from the lips of one type of cuff electrode by the buildup of connective tissue. The silastic spiral electrode appeared to be most promising for peripheral nerve stimulation, due to its ease of implantation, self-sizing properties, and lack of induction of excessive connective tissue formation. The minimal neural damage observed in these studies was attributed to surgical trauma or mechanical factors rather than electrical stimulation per se. The spiral electrode is currently being tested in further experiments in which it has been implanted on the common peroneal nerve of

cats. Neural activity is monitored by recording CAP from the cauda equina during 16 hour continuous stimulation of the anesthetized cat at stimulus currents two times the threshold for A beta fibers; no neural damage attributable to electrical stimulation has been detected.

Development of Neural Stimulating Electrodes and Evaluation of Their Electrochemical Reactions

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Sponsor: National Institutes of Health
(National Institute of Neurogical and Communicative Disorders and Stroke)

Ongoing research is aimed at developing electrode materials which might be capable of safely delivering up to 50 amps/cm^2 of geom. electrode area in 0.2 ms (10 mC/cm^2 geom. area), with biphasic charge-balanced pulses. Safe stimulation of the nervous system implies the avoidance of chemically irreversible faradaic reactions such as water electrolysis, saline oxidation, and metal dissolution. With Pt and Pt:Ir alloys, up to 0.4mC/cm^2 area (approx. 0.8 mC/cm^2 geom. area) can be injected without the occurrence of water electrolysis or saline oxidation, but a small amount of charge is lost to metal dissolution.

The anodically formed oxide on the surface of activated Ir metal was demonstrated to be exceptional in its charge injection capacity and corrosion resistance. Charge injection limits before gassing were as high as 5 mC/cm^2 geom. area for cathodic pulses, and 25 mC/cm^2 geom. area for anodic pulses. Metal dissolution was not detected.

Ir oxide films have also been deposited onto the surface of Ti and Pt:Ir electrodes by the thermal decomposition of $IrCl_3$. These thermally prepared Ir oxide films have the same electrochemical properties, mechanical stability, and corrosion resistance as the anodically formed oxide on Ir metal. Electrodes prepared with a thermal Ir oxide film on Pt:Ir or Ti had charge injection limits before gassing up to 10 mC/cm^2 geom. area for anodic pulses. Charge injection limits for cathodic pulses are currently under investigation. The electrochemical properties and stability of the thermal Ir oxide films indicate that these films would be useful for electrode applications where the physical properties of pure Ir might limit its fabrication into a practical electrode, e.g., electrodes for cochlear stimulation or muscular stimulation. Experiments are in progress to apply the technology of preparing thermal Ir oxide films to Pt:Ir electrodes currently under development for use in a cochlear prosthesis. Ir oxide coated Pt:Ir electrodes are expected to have an increased charge carrying capacity and an increased resistance to metal dissolution.

Other studies have determined that the response of the open circuit potential of thermal Ir oxide films on Ti is linear over the pH range of 2 to 10. These results indicate that electrodes prepared with a thermal Ir oxide coating may be useful for monitoring in vivo pH changes during electrical stimulation.

Artificial Sensory Transducers

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The goal of the contract is the development of force and position sensors for use on the paralyzed hand. These sensors will be used to provide sensory information to evaluate hand function in individuals for whom the hand muscles are electrically stimulated, and to provide sensory feedback to control systems for these electrical stimulators so that closed-loop control of the stimulators can eventually be achieved.

Single-element and multiple-element variable-capacitance force sensors to be located on the thumb and fingertips are currently under development. These sensors consist of metal foil parallel plates separated by a compliant polymer dielectric. The square metal foil plates range in size from 2 to 20 mm on a side, and dielectrics range from 1 to 2 mm in thickness. When aluminum foil plates are used, a dielectric consisting of silicone rubber dissolved in silicone oil gives the best results. Ratios of elastomer to oil of 1 : 1 or1 : 2 gave the best linearity, reproducibility, and lack of hysteresis.

The capacitance of the sensor is measured by an electronic sampling circuit. A fixed charge is applied to the capacitor as a current pulse, and the voltage at the end of the pulse is sampled and held. This voltage is proportional to the reciprocal of the capacitance, but since the capacitance is proportional to the reciprocal of the plate separation and hence the force, the output voltage should be linearily related to the applied force. Experimental evaluation of sensors constructed in this manner has shown them to have

highly linear characteristics over the range of forces from 0 to 9 × 10^5 dynes.

Using the structure described above or a new thick film printing technique, 64-element array sensors have been constructed. In the thick-film case, a flexible 125-micronthick Kapton film is used as the substrate and silver electrodes are printed on its surface using screen printing technology and a silver epoxy ink. The electrodes consisted of eight parallel strips 2 mm wide by 20 mm long with electrical contact pads brought out at one end. An array of 0.75-mm-square silicone rubber and silicone oil dielectric pads is then printed over the electrodes on the substrate using the same technology. As the silicone rubber begins to cure, two of these structures are pressed together with an orientation such that the long axes of the electrodes on one substrate is at right angles to those on the other. The dielectric pads bond to one another as the structure cures, and curing is completed at elevated temperatures. A multiplexing circuit to address each of the 64 capacitance elements thus formed has been designed and tested, and the sensors presently are being evaluated in the laboratory. Preliminary results show the output voltage as a function of applied force to be similar to that for the individual sensors, but the linearity is not quite as good, and there is a greater tendency toward drift in the signal.

Future plans for this work include analyzing the thick film sensors in an attempt to improve stability and linearity characteristics. Additional dielectric materials will be investigated along with variations in dielectric shape. In addition, the contract calls for investigation of thin and thick film strain gages for position sensing at the finger joints, and methods of electrotactile feedback of sensor information to the individual wearing the sensor. In the final year of the contract, sensors for temperatures and texture will also be investigated.

Adhesion Studies Program

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The Adhesion Studies Program to improve and evaluate the performance and reliability of biocompatible insulating materials used in neural prosthetic implant devices is underway at Hughes Aircraft Company, El Segundo, California.

The general objective of this program is to provide the National Institutes of Health (NIH) and the manufacturers of neural prostheses with usable and practical materials and process specifications for electrical insulation and substrate materials systems. Materials for use in the Neural Prosthesis Program must satisfy the following requirements when used in implants: the insulation shall remain bonded to the substrate, electrical continuity and function shall be maintained, and the entire system shall remain biocompatible for the functional life of the implant device.

To achieve these goals, a systematic evaluation of various dielectric materials and substrates is in progress. Specifically, four inorganic and four organic coatings were chosen for investigation. Based on initial screening studies, two polymides (DuPont's PI-2555 and Hughes Aircraft Co.'s HR605P) and a chlorinated hydrocarbon (Union Carbide's Parylene C) were selected for further study. The three were applied on interdigitated metallized test patterns for long-term aging studies. The initial electrical stress screening under immersion in water and salt solution was performed on gold metallizations. Subsequently, test fixtures were fabricated using titanium, platinum, and iridium metallizations. Adhesion to the various metals was tested both before and after surface treatments. Biocompatibility testing (in vivo) of the three coatings is underway at Huntington Medical Research Institute.

Results from long-term testing at 40 deg C in deionized water and 0.9 percent aqueous NaCl solution, with a continuous 9 volts d.c. electrical stress, have shown no deterioration of insulating properties for the PI-2555 (gold metal) after 1.6 years. This test is still in progress.

Adhesion testing on iridium, platinum, and titanium using a tape test method (ASTM D3359) after immersion at 65 deg C in 0.9 percent NaCl gave the best results with PI-2555 and HR605P on iridium and titanium metallization. PI-2555 and HR605P on platinum did not adhere as well. Parylene C adhered poorly to platinum and titanium.

There were no observable tissue reactions after 16 weeks of implantation of the three coatings on passive platinum electrodes in the subural cavity of cats. The biocompatibility studies are continuing at the Huntington Medical Research Institute. Effects of sterilization by autoclave and by ethylene oxide on the adhesion strength and electrical insulation properties of the coatings are being evaluated.

Ion-Exchange Stimulation Electrodes

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Sponsor: National Institutes of Health
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The broad goal of this program is to develop neural stimulating electrodes with large current density and charge density that utilize faradaic reactions with solid insoluble electrode products. Because such electrodes may have some toxic ionic by-products, coating with ion-specific transfer membrane to exclude contact of these ions with body tissue is being evaluated.

At the time this work was begun in 1979, only platinum electrodes employing electrical double-layer charging and tantalum oxide capacitor electrodes were viable for stimulation. Both had insufficient charge capacity for advanced types of stimulation applications. Overdriving platinum results in corrosion, generation of hydrogen and oxygen, and electrolysis of constituents of body fluid, all of which are harmful.

The first faradaic electrode chosen was silver/silver chloride since it has a known high capacity and an insoluble product. An ion transfer membrane with a high transference number for chloride ion was needed to exclude the low-solubility silver ion from contact with body tissue. A highly specific membrane was developed that could be applied in thin layers to small electrodes. An electrode was prepared that looked very promising when cycled for over 3000 hours at a current density of about 0.1 A/cm^2 in a 200 μs-per-phase biphasic pulse at 67 Hz. Unfortunately, at higher current densities a layer of porous silver grows and cracks off the membrane.

Present development is focused on avoiding the shape-change problem. One approach is to grow the porous silver layer to a steady-state thickness on the active electrode surface by pulsing, prior to coating with the membrane. Another approach is to develop more pliable membranes less subject to cracking. Development is still in progress to solve the shape-change problem. Other electrodes also are being considered, such as iridium oxide which has recently come into prominence.

Mathematical modeling calculations of temperature rise and pH change were made to gain a better understanding of limitations to use of stimulating electrodes. Temperature rise by joule heating and other irreversible effects does not appear to be a problem now, but could be a limitation for future, micrometer-size electrodes operated at greater than 10 A/cm^2. Calculations show that pH changes can be very large at oxide electrodes during biphasic pulses, but the pH excursions extend only a few micrometers away from the surface. The practical significance of such pH excursions is as yet unknown.

A possible side benefit of the membrane-coated Ag/AgCl electrodes is that they may be useful as in vivo microelectrodes for chloride sensing. Some effort is continuing on the preparation of microelectrodes for evaluation■

Capacitor Stimulating Electrodes for Activation of Neural Tissue

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Sponsor: National Institutes of Health
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The overall goal of this program is to develop highly miniaturized capacitor-type intracortical stimulating electrodes suitable for the chronic electrical stimulation of highly selective neural elements, thus contributing to the development of advanced neural prosthetic devices for the treatment of various disorders. Ideally, these electrodes should be mechanically stable, biologically compatible as implants, and useful over a long period of time. The latter two conditions also imply absence of corrosion and toxic species formation over a long, useful life.

An initial short-term objective was to develop cylindrical shaped and conically tipped microstimulating electrodes (100 microns in diameter and 200 microns in active length) capable of storing at least 20 nanocoulombs within 0.1 milliseconds without exceeding 4 volts (corresponding to a minimum charge injection density of 2.3 nC.cm^2). Ultimately, for single neuron stimulation, the electrode will have to be further miniaturized to approximately 5 microns in diameter and 7 microns in active length. The electrical requirements in terms of current and charge densities are 50A/cm^2 and 20 mC/cm^2, respectively.

During the course of this program, high-surface-area tantalum capacitor electrodes were prepared by either a slurry dip or electrochemical etching process. In the 100-micron-diameter configuration, the charge injection density was found to exceed 6.4 nC/cm^2, which effectively ensured a higher safety margin in neural stimulation. The leakage current at 4 V was of the order of 0.1 nA/nF, which is quite acceptable for neural stimulation. Furthermore, a series of fabrica-

tion procedures also was developed in order to prepare complete microelectrode assemblies with insulation and electrical leads ready for implantation. A number of such complete stimulating electrode assemblies were prepared, characterized, and delivered to NIH-NINCDS for in vivo testing.

In addition to tantalum, other potentially attractive metal/metal oxide systems, including titanium, niobium, hafnium, and zirconium also were studied. The most promising system discovered to date is the titanium/titanium dioxide system. A novel oxide formation method, developed in this program, permits titanium electrodes to operate in a hybrid capacitor/faradaic mode. Essentially, a reversible redox reaction of the oxide film thus formed would enable the electrode to handle safely a charge density of the order of 20 mC/cm^2 per pulse, which meets the ultimate goal of the program.

The present effort is focused on the optimization of this oxide-forming technique and evaluation of the performance of these electrodes over long periods of time in vitro. Specific electrode fabrication techniques also are under development in order to produce smaller microelectrode assemblies suitable for in vivo testing in the near future■

Capacitor Stimulating Electrodes for Activation of Neural Tissue

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Introduction—A common concern of any neural prosthetic device, whatever its application, is the operation of the stimulation electrode. For intracortical neural stimulation, the electrode must be able to inject substantial quantities of charge without deleterious irreversible faradaic reactions occurring across the electrolyte-tissue interface. With a capacitor electrode, an insulating dielectric layer on the surface of the electrode allows charging of the electrode while preventing the passage of the electronic current necessary for the faradaic reactions. Ta/Ta_2O_5 capacitor electrodes on high surface area substrates have been used successfully for neural stimulation where moderate charge densities are required.

In this program, we have attempted to make a smooth, high-charge-density electrode by using films of barium titanate ($BaTiO_3$) which can have a dielectric constant of up to a hundred times that of tantalum oxide. Because of the inverse dependence of the capacitance on the film thickness, however, the films must be made as thin as possible without causing excessive leakage current during their operation. We have deposited $BaTiO_3$ films by sputtering onto Pt substrates, and tested their electrical properties in phosphate-buffered saline.

Methodology—The films were deposited onto planar Pt substrates by rf sputtering in an Ar/O_2 atmosphere. Films were made with thicknesses from 1 to 2.5 μm. The substrate temperatures ranged from ambient to 940 deg C. After the deposition some of the films were annealed in air at temperatures from 900 deg to 1200 deg C for periods up to 6 hours. The structure of the films was determined by X-ray crystallography; the morphology and coherence by electron microscopy.

The electrical properties of the films were measured using diluted phosphate-buffered saline as the top contact. The AC capacitance was measured with a capacitance bridge at frequencies from 0.5 to 10 kHz. The DC leakage current was measured for positive biases with an electrometer or picoammeter.

Results—The films had to be annealed above 1000 deg C in air before the pure, crystalline $BaTiO_3$ phase was formed. This annealing, however, led to formation of large crystallites and a porous structure. For films of 1.2 μm or less, areas of the exposed Pt substrate were observed by electron microscopy. The capacitance of the 2.5 μm films was 2.5 $\mu F/cm^2$ when measured in the liquid electrolyte. This high capacitance, which corresponds to an effective dielectric constant of 7000, resulted from the large surface area associated with the porous structure. Unfortunately, the high capacitance was accompanied by a high DC leakage current due to the contact of the electrolyte directly with exposed areas of the Pt substrate. The as-deposited, unannealed films had an amorphous structure and a much lower leakage current, but their dielectric constant was less than 100.

Conclusions—As a result of our work on $BaTiO_3$ and anodic oxide dielectric thin films, we do not view as very promising the ultimate success of making useful capacitor electrodes with the smaller dimensions necessary for single neuron stimulation. A more fruitful direction of research is the investigation of thin film materials that use surface redox reactions to accomplish charge transfer without permanent altera-

tion of the solution composition. One material of this type currently under investigation in our laboratory is iridium oxide.

Multichannel Multiplexed Intracortical Recording Arrays

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Sponsor: National Institutes of Health
(National Institute of Neurological and Communicative Disorders and Stroke)

This project seeks to develop multielectrode recording arrays that can be implanted directly in the cortex and that are capable of recording the electrical activity of single neurons over long periods of time (months to years). By allowing neuronal activity to be recorded simultaneously from many cells spaced in depth through the cortex, these probes should constitute a major advance in instrumentation for studying the central nervous system. Significant progress in understanding the information-processing techniques active in neural structures should occur, and understanding these will, it is hoped, lead to improved understanding of a variety of neurological disorders. The ability to record the signature activity from neurons at many points through the cortex for external processing by a microcomputer also offers the hope of being able to close the control loop in a variety of neural prostheses, allowing stimulation to be conditioned on responses (or command signals) from the body itself.

In the probe structure under development, the supporting substrate for the electrode array is silicon, formed from a wafer by selective chemical etching. Typical dimensions include an overall length of 3 mm, a shank width of 60 μm, and a substrate thickness of 15 μm. The upper surface of the probe is insulated with silicon dioxide and silicon nitride dielectrics on which are deposited thin-film interconnect leads of polysilicon or tantalum. These leads are insulated with overlayers of silicon dioxide and silicon nitride, which are selectively removed over the recording sites to permit lead contact to the extracellular fluid. At the rear of the probe, integrated circuitry is formed to allow the very small neural signals to be amplified and then multiplexed to the outside world on a single wire. This circuitry allows the number of wires which must be attached to the probe to be limited to only 3 for as many as 40 recording channels.

A batch process has been developed for producing these probes with high yields. A prototype integrated circuit for amplifying and multiplexing up to 12 recording channels has been fabricated and tested successfully. The required chip area is 1.75 mm^2 in 6 μm/feature NMOS technology. Passive probes (without on-chip circuitry) having as many as 10 channels have been fabricated and are now being tested using short-term experiments in animals. Neural activity has been recorded from both tip-mounted and side-mounted recording sites, with signal-to-noise ratios exceeding 5:1. These results are very encouraging in regard to the eventual successful application of the fully integrated probe structure.

During the next phase of this project, primary effort is being directed at the further study and optimization of probe/recording-site geometries to best recording characteristics, and at the successful integration of the signal-processing circuitry directly on the probe. Efforts also are directed at the development and evaluation of long-term implantable probe assemblies, including improved insulating materials capable of preserving their electrical integrity in the face of long exposure to saline.

2. Upper Limb Applications

Restoration of Upper Limb Function Using Functional Electrical Stimulation (FES)

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

The focus of research activities in the Case-Western Reserve University Rehabilitation Engineering Center is directed toward restoration of upper limb function. Projects at this time include restoration of motor function through functional electrical stimulation, closed-loop control of electrically stimulated muscles, and electrotactile stimulation for sensory augmentation.

These studies are the core area of research in the program. The purpose of the project is to develop and evaluate systems employing functional electrical stimulation to provide control of hand movement.

Closed-Loop Control of Electrically Stimulated Muscles

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Sponsor: National Institutes of Health
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The objectives of this research project are to design and evaluate closed-loop control systems for the regulation of grasp and release in functional neuromuscular stimulation orthoses. Systems will be implemented for lateral pinch and palmar prehension in C5 and C6 quadriplegic patients to provide repeatable input/output properties, regulation of grasp stiffness, and coordination of multiple channels of stimulation with a single command signal.

The stiffness regulation system consists of two feedback loops; one is an internal force regulation loop that modulates stimulus pulse width and interpulse inverval; the other is an external position feedback loop with a stiffness controller that regulates the relationship between force and position. All elements of the stiffness regulation system have been (and are being) tested in animal experiments. The results of those tests are being applied in the design of the hand-grasp regulation systems.

In the initial part of this study, we have concentrated on systems identification of the stimulated muscles and evaluation of the response properties of the closed-loop force feedback system. In these tests, the subject's hand is held stationary with the appropriate digit resting against a stationary force transducer. The control systems are implemented by software in a laboratory microcomputer.

Systems identification of the force modulation of electrically stimulated muscles consists of three phases: (i) estimation of the muscle fusion frequency (i.e., the frequency, at which there is 10 percent ripple in the force), (ii) measuring the recruitment characteristic (steady-state relationship between pulse width and force, measured at the fusion frequency), and (iii) estimation of the muscle dynamic properties. The muscle dynamic properties are modeled by a discrete time difference equation relating the force output at each stimulus instant to the two previous force outputs and the previous recruitment modulation parameter. When static recruitment nonlinearities are removed, the linear model predicts the actual force output with an error less than 10 percent. These results are in agreement with our results from animal studies.

The stability, rise time, overshoot, and settling time of the closed-loop force regulation system are measured from responses to step changes in command. Responses are also evaluated for ramp command inputs, since ramps are more representative of the types of inputs generated by patients. The criteria for acceptable step responses are (i) rise time (0 to 90 percent) less than 1 second, (ii) overshoot less than 20 percent, (iii) settling time (± 5 percent of steady state value) less than 2 seconds, and (iv) no sustained oscillations in the output at the stimulus instants.

It was possible to meet these criteria with a wide range of controller parameters (e.g., a gain range of 5 to 10) indicating that the system was robust (insensitive to controller or muscle parameters). These results are also in agreement with previous animal studies.

Future plans include similar evaluation of the complete stiffness regulation system, which has been implemented in software. Testing will be expanded to include evaluation of the patient's ability to control the closed-loop systems.■

3. Lower Limb Applications

Walking Restored in Paralyzed Man Using Electronic Orthotics

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

This is a 3-year research program which began in September 1983; it is a continuation of earlier work of functional electrical stimulation of paralyzed muscles. The goal of the work is the development of a neuromuscular orthotics system to provide paralyzed persons with specific functional activity. As compared with the existing prototype system the new one should yield smoother performance, improved stability, reduced fatigue, and be adaptable to an implantable form.

Nine paraplegic patients with complete lesions ranging from T-4 to T-11 have participated in the study. Seven of these are currently active subjects. They are implanted with percutaneous intramuscular electrodes in major muscles of the legs and pelvis which deliver stimuli for flexion and extension of the hip, knee, and ankle. Either a laboratory computer or a portable microprocessor-controlled stimulator pro-

vides programmed, sequential electrical stimuli to produce desired combinations of movements for standing up, level walking with either right or left leg, and going up or down stairs.

With this instrumentation all patients have developed clinically usable muscle forces. Their exercise program includes using electrical stimulation for an hour a day and walking for half an hour three times a week. Quadriceps muscle force and girth of the thigh increased over a period of several months of exercise. The patient's aerobic capacity is monitored using an arm-ergometer. All patients are able to tolerate a 50 to 100 percent increase in workload with lower heart rate and lower blood pressure than that recorded for the same workloads at the start of the exercise program.

Among the six patients who have been able to walk with electrical stimulation, the total number of electrodes implanted ranged from 36 to 108. The electrodes, made of 76μ, multistranded stainless steel, were generally well tolerated; over the course of 9 months, electrode failure varied among the patients from 25 percent to 50 percent. The failure was either mechanical or due to physical movement where response to stimulations was no longer functional. At the time of this communication, four patients were able to walk with a standard walker for distances ranging from 3 m to 50 m, and two were able to walk only in parallel bars. The major problems encountered were poor balance due to lack of functional hip muscles, high energy requirements, and non-related medical complications.

During the past year three major improvements in the neuro-orthotic system have been developed. In almost all patients the capability for dorsi and plantar flexion has been added through implantation of peroneous longus, tibialis anterior, and soleus muscles of the lower leg, eliminating the earlier need for an ankle-foot orthosis. In two patients postural control has been improved by the implantation of hip extension muscles. One patient is able to climb and descend stairs holding onto rails. A closed-loop, or feedback, control has been implemented, allowing the computer to adjust the levels of stimulation according to the knee angle during standing, thus minimizing the amount of stimulation delivered to the muscles and reducing fatigue.

Future work is directed toward (i) improvement in electrode design and implantation technique, (ii) improvement in stability and smoothness of motion through the implementation of closed-loop controllers of electrical stimulation using an improved mathematical model of human gait, and (iii) evaluation of sensor needs and design of those necessary for the closed-loop system■

[See also **II. Orthotics, A. Lower Limb**, An Investigation into the Mobility of the Cerebral Palsied Child]

4. Other

Active Physical Therapy: Application of FES to Rehabilitation Medicine

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This pilot project has begun to examine in detail the effects of isokinetic and dynamic exercise on paralyzed skeletal muscle and on the cardiorespiratory and skeletal systems. The overall goal of the studies will be to train a large number of paraplegic and quadriplegic subjects (with injuries at various levels of the spinal cord) by each of the two exercise modalities, and then to study the responses of the cardiovascular, respiratory, and skeletal systems.

Isokinetic exercise is often used to condition muscular strength. Isokinetic exercise involves lifting weights very slowly up and very slowly down with sufficient load applied to a muscle to fatigue it fairly rapidly. This type of exercise, while conditioning muscular strength, has historically been very poor in terms of developing cardiorespiratory fitness. To condition the cardiorespiratory system physically, training such as aerobic exercise must be used. In contrast to isokinetic exercise, aerobic exercise involves the rapid movement of muscle against a light load at a sufficient level so that the muscle can produce energy (through the utilization of oxygen-consuming pathways in the muscle). While applying to nonparalyzed individuals, such responses may or may not apply to the paralyzed because of the possible disruption of many autonomic pathways resulting from the spinal cord injury.

The purpose of the current series of experiments has been to examine various training protocols involving isokinetic and dynamic training of skeletal muscle and other body systems. Included in the parameters examined have been the effect of various exercise training programs on muscular strength, muscular endurance, muscle size, limb size, limb blood flow, bone mineral density, cortical bone thickness, blood pressure at rest, blood pressure during

exercise, heart rate at rest, heart rate during exercise, orthostatic tolerance at rest, drug tolerance, pulmonary function at rest, ventilation and ventilatory equivalent during exercise, lactic acid production in the blood during exercise, acid base balance at rest and during exercise, and exercise efficiency as assessed by oxygen uptake for a given exercise regime. Further studies also will be performed to examine the thermoregulatory stresses induced by these forms of exertion.

Electrical stimulation is delivered sequentially to skeletal muscle by three electrodes placed on the surface of the skin. Using carbonized rubber electrodes, stimulation is applied with a pulse width of 300 microseconds and a frequency of between 20 and 40 hertz. The amplitude of the signal is modulated to control the degree of recruitment in the underlying skeletal muscle below the electrodes. The degree of recruitment (and therefore the strength development) of the skeletal muscle was then controlled according to the computer program adjusted for the desired position of the leg during isokinetic or dynamic exercise (closed-loop control). The closed-loop control system employed throughout these experiments used the position of the limb as feedback.

During the first 9 months of the work (which is projected to extend over a number of years), experiments were conducted to collect baseline data on the cardiorespiratory responses during isokinetic and dynamic exercise.

Closed-loop electrical stimulation was used to induce isokinetic contractions in skeletal muscle of eight paralyzed individuals and to examine their cardiorespiratory responses to that form of exercise. (Four nonparalyzed subjects also were evaluated during similar but voluntary exercise as a basis of comparison with the paralyzed subjects.)

After 6 weeks of training, an experimental session was conducted during which cardiovascular and respiratory parameters were recorded during 4-minute periods of exercise at progressively increasing intensities for all subjects. Results indicated that the training program has caused an average increase in the circumference of the thigh of the eight spinal cord injury (SCI) subjects of 2.7 cm ($\pm$0.6 cm). This was paralleled by an increase in strength of the quadriceps muscle group, which averaged 4.9 kg ($\pm$2.8 kg). When the cardiovascular responses during 4-minute bouts of exercise were measured, it was shown that even during the most fatiguing bouts of exercise, the average cardiovascular responses were small. Heart rate increased from 83 beats per minute at rest to 101 beats per minute at the end of exercise, while blood pressure increased from a mean resting pressure of 96 mm Hg at rest to 115 mm Hg at the end of exercise in the paralyzed subjects. There were significant differences (in the heart rate and blood pressure responses to exercise) of the paraplegic and quadriplegic subject.

Another four paraplegic, four quadriplegic, and four control subjects participated in a second series of experiments on a modified Monark bicycle ergometer to examine the effects of electrical stimulation on the cardiorespiratory responses that occur during dynamic exercise. The cardiorespiratory responses during exercise were then examined in these same subjects and compared to those of nonparalyzed controls in an additional exercise session. Both groups of subjects had similar responses to exercise. However, the magnitude of the heart rate and blood pressure responses to the exercise were different in the three groups of subjects. The differences were apparently related to the degree of damage in the autonomic nervous system associated with the spinal cord lesion that initially resulted in the paralysis. However, aerobic exercise had many beneficial effects on paralyzed individuals that may help them attain better health.

Finally, during this period of time, pilot experiments were started to assess the effect of physical training on drug tolerance of the body. Also, the initial thermoregulation experiments were started, with subjects doing armcrank ergometry in a heat chamber, to assess thermoregulatory tolerance during exercise. As the work continues these areas will be expanded until the full objectives of the study can be realized■

Influence of Sural Nerve Stimulation on Motor Unit Control in Normal Subjects and Those with Spastic Paresis

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Introduction—Stimulation of touch and pain afferents can modify muscular activity in a manner appropriate to the stimulus; i.e., the foot withdraws on painful stimulation. Spinal-polysynaptic reflexes are modifiable by supraspinal influences. Anticipation can enhance responses, while repetitive stimulation will lead to habituation and attenuation of response. In patients with lesions of the spinal cord causing impairment of conduction in descending motor pathways, spinal-polysynaptic reflexes are disinhibited.

The most commonly observed response in the lower extremities is the flexion reflex. This reflex can occur spontaneously or on very minimal mechanical stimulation of the limb. On the other hand, pressure applied to the sole of the foot may elicit forceful plantar flexion.

Partial involvement of descending motor pathways may permit the patient to extend the lower extremities and even to stand. The antigravity posture of plantar flexion and lower extremity extension can be voluntarily increased. Muscle activity tends to persist for seconds after voluntary activation ceases. It is very difficult or impossible for such patients to voluntarily flex the lower extremity in order to step. At the same time, flexor spasms occur frequently in response to nociceptive and other skin stimulation.

While recording from single motor units in first dorsal interosseous, extensor digitorum indicis, and flexor digitorum profundus, electrical stimuli delivered to the flexor and extensor surfaces of the fingers produced transient inhibition of motor unit firing. Cutaneous afferents have been demonstrated to modify excitability of motor neurons.

Some patients with spastic paresis have discovered that transcutaneous nerve stimulation applied to the involved extremity (sural nerve) improves muscular strength and control. This observation suggests that appropriate stimulation of sensory nerves might result in facilitation of motor neurons, making them more accessible to residual corticospinal innervation. Such stimulation might also increase activity in polysynaptic flexor reflexes, making it easier to oppose voluntarily the antigravity posture. Intermittent extension and flexion of the lower extremities could be induced by appropriate activation of spinal reflexes.

Methodology—The subjects were seven normal adults, two females and five males. Five patients with multiple sclerosis resulting in spastic paraparesis preventing ambulation or ambulation only with bilateral support and two patients with corticospinal tract disease resulting from amyotrophic lateral sclerosis were studied.

In this preliminary study, the influence of electrical stimulation of the sural nerve upon voluntary control of the tibialis anterior muscle was investigated. Tonic stimulation at a nonpainful level insufficient for activation of the flexor nociceptive reflex was used. The influence of stimulation upon single motor unit control and the force of maximum dorsiflexion of the foot was investigated. Normal subjects and those with weakness resulting from involvement of descending spinal motor pathways were studied.

Biomechanical Measurements—The patient was placed in a supine position with the right leg supported on a 1-inch styrofoam pad. The heel of the foot was free of the support surface. The foot was allowed to assume a slightly plantar-flexed rest position. It was then attached to a Grass strain gauge by means of a lightly padded leather strap and cable. The loop of the strap circled the foot just proximal to the metatarsalphalangeal joint, so that toe movement would not interfere with the measurement of force of dorsiflexion. The strain gauge was connected to a DC amplifier set to produce an approximately 0.5 kg/cm deflection.

Sensory Nerve Stimulation—Two silver disc electrodes set in plastic and 2.5 cm apart were placed over the sural nerve at the level of the malleolus, with the cathode proximal. Square wave pulses of 0.05 to 0.1 msec duration at an intensity of approximately 50 to 100 V were applied at a level just sufficient to produce a "tingling-warm" paresthesia. For patients with spastic paresis, the level of stimulation was kept below that sufficient to produce dorsiflexion of the great toe or a flexion reflex, even upon stimulation lasting several minutes. Stimulus frequency and intensity were kept constant throughout the experiment.

Recording of Tibialis Anterior Motor Unit Activity—A 26-gauge monopolar needle electrode was inserted into the tibialis anterior muscle, and a single motor unit was isolated during minimal voluntary muscle contraction. Using auditory feedback of the motor unit potential to establish control, the subject became familiar with the level of effort required to activate a single motor unit and sustain its firing. During dorsiflexion of the foot and single motor unit activation, the force was measured simultaneously. The subject was then requested to dorsiflex the foot repeatedly to a level just sufficient to activate a single motor unit.

Experiment 1—Single Motor Unit Control—The subject was instructed to maintain steady firing of a tibialis anterior single motor unit during measurement of force. Following 1 minute of steady firing, audio feedback was discontinued for a period of 30 seconds. Sural nerve stimulation was then begun and continued for 30 seconds to 1 minute. Additional experiments in which the audio feedback was discontinued for periods up to 2 minutes also were performed on the same subjects.

Experiment 2—Maximal Effort—The subject was instructed to dorsiflex the foot maximally in three

trials. He/she was then told that during the next trial there would be concomitant stimulation of the sural nerve. Finally, three additional trials of maximal effort were made immediately following those accompanied by sural nerve stimulation.

Experiment 3—Following three maximal dorsiflexions the sural nerve was stimulated for a period of 5 minutes. Three maximal dorsiflexions were then repeated.

Results

Normal Subjects—Single Motor Unit Control—All subjects were able to maintain stable firing of tibialis anterior motor units in the absence of audio feedback for 30 seconds or more. Sural nerve stimulation (SNS) uniformly resulted in increased firing rate and often recruitment of additional motor units. The corresponding increase (greater than 20 percent) in force of dorsiflexion was also recorded. A two-fold to three-fold increase in force was not unusual. In several trials one subject habituated to the stimulus and did not increase tibialis anterior motor unit firing rate. All subjects experienced a definite increase in the level of effort required to maintain a stable level of tibialis anterior activation. SNS was experienced as a weight or force promoting plantar flexion.

Maximal Effort—In the two female subjects, it was possible to assess the influence of SNS upon maximal effort. In each of three trials the force of dorsiflexion was reduced.

Multiple Sclerosis Patients—Single Motor Unit (SMU) Control—SMU control in the absence of audio feedback was unstable or impersistent in three-fifths of the multiple sclerosis (MS) patients. SNS causes SMU firing and force to decrease in three-fifths and increase in two-fifths of the patients. All patients reported an awareness of increased effort required to maintain stable activity in tibialis anterior.

Maximal Effort—Maximal effort was tested in three patients. In all three, the force of dorsiflexion increased by 50 percent or more following sensory nerve stimulation. The effect was followed for up to 20 minutes. In two subjects, a period of 5 minutes of SNS without muscle contraction resulted in a progressive increase in force or dorsiflexion over a period of 10 to 15 minutes. In two patients, SNS during maximal contraction caused a decrease in force, and in one subject, an increase.

Patients with Corticospinal Tract Disease—Amyotrophic Lateral Sclerosis—In the small sample of two patients, SMU firing was stable in one subject but unstable in the other, in whom a progressive increase in firing was noticed in the absence of audio feedback. SNS caused a decrease and an increase respectively in the subjects. The sense of effort was increased in both subjects during SNS.

Maximal Effort—In both subjects the force of maximal contraction decreased with SNS, but increased following stimulation.

Discussion—Results from this small number of subjects are not conclusive. However, some consistencies are present. All subjects experienced an interaction with the stimulus, the net effect of which was an awareness of increased effort required to maintain tibialis anterior contraction at a stable level. Variability in force output during SNS can be explained in part by varying degrees of voluntary effort applied to counter the apparent resistance to dorsiflexion. Even in normal subjects, maximum dorsiflexion may be decreased by simultaneous sensory nerve stimulation.

In MS patients the influence of SNS upon single motor unit control was more variable. The ability to counteract the resistance to dorsiflexion was compromised. Also, in these patients, the increased force of dorsiflexion seen with SNS might result from the simultaneous activation of flex or reflex afferents. All subjects manifested an increased force of dorsiflexion following SNS. Some subjects reported that the experience was similar to exercising against a weight.

The final effect of increased force of dorsiflexion following SNS may be similar to post-exercise facilitation. Inhibition of dorsiflexion produced by SNS may result in greater levels of excitatory transmitter in the spinal cord during voluntary attempts at dorsiflexion. When the inhibition stops, then enhanced excitability persists.

SNS may find practical use, since the patient may not need to dorsiflex against resistance in order to improve the strength of dorsiflexion.

Further experiments will examine the effect of SNS upon maximal effort and SNS without muscle contraction upon the maximal strength of dorsiflexion following stimulation. The duration of this interesting effect also will be examined. Additional subjects must be tested using the above protocol■

Effect of Electrical Stimulation and Passive Stretch on Peripheral Nerve Disorders

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Sponsor: National Institute of Handicapped Research

The loss of innervation to skeletal muscles of patients with peripheral nerve injuries can lead to complete degeneration of the muscles. The goal of this study is to establish the significance of specific treatment modalities (electrical stimulation and passive exercise) employed to overcome the state of muscle inactivity, retard muscle atrophy, improve the microvascular system, and enhance reinnervation and functional recovery.

The specific objectives of this study are to critically determine by histochemistry, light and electron microscopy, and by electrophysiology, if the above two treatment modalities are beneficial in (a) the short-term and long-term management of peripheral nerve injuries as well as (b) enhancing subsequent reinnervation. These parameters will be determined in the extensor digitorum longus muscle of rat.

This study has immediate relevance to rehabilitation of neuromuscular dysfunction. Considerable effort is expended by therapists to overcome the degenerating effects of skeletal muscles due to loss of innervation. Loss of innervation may be incurred by denervating diseases, some myopathies, accidental or purposeful nerve injuries, and limb reimplantation. The usefulness of some treatment modalities (electrical stimulation and passive exercise) currently employed to treat these conditions have not been established or are controversial. Questions as to their precise benefit to the recuperating patient are still largely unanswered. The present study addresses these problems and is designed to define the benefits and increase our understanding of the above two therapeutic modalities.

It is anticipated that therapy programs involving the use of electrical stimulation and passive exercise will be based on the results of our project. A more efficient protocol may then be established to aid the disabled to gain functional recovery in the shortest possible time, and to improve their employment chances, as well as independent living prospects■

Fitness Improvements and Physiological Responses to FES Exercise

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Our several years of research in upper body exercise for the disabled (wheelchair/armcrank ergometry), and more recently in functional electrical stimulation (FES) exercise of paralyzed leg muscles, suggests that higher levels of physical fitness may be achieved with combinations of these exercise modes. FES exercise can result in marked increases in strength and endurance capability. It also may improve the integrity of the bones.

However, little data are available concerning metabolic, cardiovascular, and pulmonary responses to this form of exercise and how these responses differ from those for able-bodied individuals performing the identical exercise task voluntarily. Because autonomic sympathetic nervous system control in many of these patients may be limited or absent during this peripherally induced exercise, organ system responses may be inadequate for the metabolic demands of the contracting muscles, which would severely limit performance. It is particularly important to determine whether blood flow to the electrically stimulated muscles is sufficient and whether critical variables such as arterial blood pressure and muscle temperature are within safe limits. Thus, further understanding of physiological responses to FES exercise seems necessary to reduce potential risks to patients using FES for exercise therapy and for locomotive activities.

In contrast to FES exercise, voluntarily performed arm exercise in paraplegics appears to elicit similar metabolic, cardiovascular, and pulmonary response patterns as for able-bodied individuals performing the same exercise. Thus, sympathetic influence of organ system control appears to be functional with this form of exercise. Conditioning protocols utilizing wheelchair and armcrank ergometry have been shown to be effective in improving the performance of the upper body musculature, and potentially promoting some degree of cardiovascular and pulmonary fitness. However, high levels of aerobic conditioning cannot be expected with arm exercise because the relatively small skeletal muscle mass employed usually tends to fatigue prior to the cardiovascular and pulmonary systems receiving exercise of sufficient intensity and duration to cause training effects.

Ideally, aerobic conditioning requires an exercise mode that utilizes a large skeletal muscle mass. In this way, greater demands can be placed upon the cardiovascular and pulmonary systems while reducing the effects of local muscle fatigue. Applying this principle to paraplegic patients, greater skeletal muscle mass for exercise may be incorporated by simultaneously exercising the arms (voluntarily) and the paralyzed legs (FES). This complex mode of exercise may promote upper body and lower body fitness as well as cardiovascular fitness. It also seems possible that this complex mode of exercise will permit better performance of the electrically stimulated legs (than for FES leg exercise alone) because sympathetic nervous system adjustments to exercise would be stimulated by the voluntary arm exercise.

Because of the potential for improving the physical fitness of paralyzed individuals, more research needs to be performed in: developing protocols for FES exercise; evaluating physiological response to FES exercise; and evaluating the combination of FES and voluntary exercise for aerobic conditioning.

The goal of our research project is to improve rehabilitation of individuals with lower limb paralysis or paresis resulting from spinal cord injury or stroke. A primary need for individuals is the improvement of their physical fitness. To accomplish this goal, two specific long-term objectives (with their short-term objectives) are proposed:

1. To evaluate the effectiveness of exercise programs incorporating electrical stimulation of paralyzed muscle for their potential in improving muscle strength and endurance, bone mineralization, and general physiological fitness.

a. Develop standardized exercise protocols utilizing electrical stimulation of paralyzed muscles to provide safe and effective means of evaluating muscle performance.

b. Develop exercise conditioning protocols for enhancing the capacity for aerobic and anaerobic exercise in electrically stimulated paralyzed muscles.

c. Compare metabolic, cardiovascular, and pulmonary responses to electrically induced exercise of paralyzed muscles with the same exercise tasks being performed voluntarily by able-bodied individuals.

2. To evaluate the effectiveness for aerobic conditioning of exercise protocols that incorporate simultaneous electrically induced exercise of paralyzed legs and voluntary exercise of the arms.

a. Determine peak oxygen uptake and cardiopulmonary responses for electrically induced leg extension exercise and armcrank/wheelchair ergometer exercise performed separately and in combination.

b. Determine changes in the capacity of paraplegic individuals to propel manual wheelchairs following upper and lower body exercise programs■

Weight Transfer Training Using Biofeedback and Electrical Stimulation in Strokes and Incomplete Spinal Cord Transections

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Hypothesis—Patterned electrical stimulation of lower extremity muscles will facilitate patient awareness of the involved leg, transfer of weight to the leg, and assist therapists in teaching standing balance and weight transfer.

Method—Design and construct a weight-bearing test device, weight transfer apparatus, force feedback display and electrical stimulators. Study and control groups will be observed to determine if weight-bearing, gait, endurance, energy expenditure, and ambulation level are altered by patterned electrical stimulation.

Goal—Improved gait training program for patients recovering from certain neurological conditions, shortening hospitalization time, and an improved level of ambulation■

[See also **IV. Spinal Cord Injury, B. Medical Treatment**, The Effect of Electrical Stimulation of Muscles on the Cardiovasculatory System and **C. Spinal Cord Regeneration**, The Effects of Application of Direct Current on Regeneration of Nerve Cells]

V. Functional Assessment

Development of a Computer-Automated System for Functional Assessment

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Investigators at the University of Texas at Arlington (UTA) have developed a computer-automated system to quantitatively assess a broad selection of sensory and motor functions. The objectives of this project are to further develop and expand the basic system, and to prepare two complete prototype systems for clinical evaluation and application studies at our clinical settings, the University of Texas Health Science Center at Dallas (UTHSCD), and the Dallas Rehabilitation Institute (DRI). In this battery of tests, each function is assessed by having the test subject carry out very specific, simple, and short-duration tasks that usually involve responding to computer-generated stimuli. Special-purpose transducers have been designed to convert responses into voltages suitable for digitization by computer. For most tests, algorithms compute single-number results that quantitatively indicate the level of a specific function. Software for test administration, and for printing of formatted results, has been developed. New software to graphically indicate composite and specific function results, as well as their change over time, is under development.

Over the past year, the basic system was redesigned to improve performance and to facilitate modular expansion and replication. In 1984 a prototype of the redesigned basic system was completed and placed into clinical evaluation at UTHSCD during January and a second identical prototype was placed at the DRI in June.

Since more than 250 measures can be obtained, a sensory and motor function data base structure was defined and implemented on a mainframe computer. Data recorded for each subject is transferred via modem to be entered into the data base.

New tests are being developed for incorporation into the system. A device that measures pronation and supination strength, speed, and range of motion was added in June 1984. A prototype of a three-dimensional digitizer, called the bio-curve tracer, also was completed. This device was designed for accurate range-of-motion measurements about all body joints, as well as for handling entry of anthropomorphic data directly into the computer. Clinical studies are now in progress to evaluate reproducibility, and to develop a test administration protocol for this device.

Progress was made on another device that is capable of measuring isometric and isokinetic strength, resistance to passive motion (rigidity and spasticity), and proprioception about specific joints. The device is similar to a previous one for resistance to passive motion measurement. A first version completed recently is used to assess these functions about the finger and wrist joints. A second is being fabricated for knee and elbow evaluations. These devices will be incorporated into the clinical systems by December 1984.

Inquiries were received from other institutions about the possibility of replicating the sensory and motor-function system for use in their own research. In accordance with our intention to promote quantitative, objective assessments, arrangements have been made to respond to a limited number of such requests, with our center replicating the system at cost. Data obtained at remote locations would be included in the sensory and motor function data base.■

Clinical Evaluation and Application of a Computer-Automated System for Functional Assessment — Part I

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Sponsor: National Institute of Handicapped Research
The Dallas Rehabilitation Foundation

The first prototype of this center's redesigned computer-automated functional assessment system, developed by the University of Texas at Arlington (UTA) investigators, is being evaluated for test-retest repeatability, effects of age, gender, and handedness, and for stability of patient data. The clinical setting at the University of Texas Health Science Center at Dallas (UTHSCD) includes functional assessments of patients with progressive neurologic diseases such as

Parkinson's disease, multiple sclerosis, myasthenia gravis, and Huntington's disease, as well as a major emphasis on those with chronic low back pain. The function of carefully screened normal subjects, aged 20 to 80 years of age, will be determined to form a data base that will be used to indicate a patient's function in terms of percentile of a normal population of appropriate age range and gender. Over the 4-year period of FY84 through FY87, it is expected that over 300 normal subjects and 400 patients will be evaluated during the course of these studies. As of June 1984, 125 subjects have been tested in the clinic. Emphasis has been placed initially on evaluating the system and test administration personnel, as well as on establishing the normal function data base. The data base is essential in order to express results of patient evaluations in a form that will facilitate interpretation and that will provide clinicians with feedback useful in evaluating their progress in restoring or preventing loss of functions.

The data base is currently in a rough format in that it contains a sufficient number of subjects (from past as well as present efforts) to establish young (18 to 40 years) adult and old (41 to 80 years) norms for 150 different measures of sensory and motor function. As the sample total grows, efforts will be directed toward establishing norms for each decade for each of the more than 250 measures in the system. This task is greatly facilitated by the nature of the system's automated data acquisition and result logging design. The majority of these measures can be obtained in a 2-hour test session.

Clinical Evaluation and Application of a Computer-Automated System for Functional Assessment — Part II

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Sponsor: National Institute of Handicapped Research
The Dallas Rehabilitative Foundation

A second prototype of this center's computer-automated functional assessment system is being evaluated clinically at The Dallas Rehabilitation Institute (DRI). Work was recently begun to evaluate the function of patients with head injuries, spinal cord injuries and peripheral neuromuscular damage, adult cerebral palsy, amputated limbs, and spina bifida. Data will be used to develop functional profiles of these conditions, as well as to form a sensory and motor function data base. DRI investigators will work in close collaboration with those at the University of Texas at Arlington (UTA) and the University of Texas Health Science Center at Dallas (UTHSCD) to improve test devices as experience with these patient groups is obtained.

Another sub-project will compare data acquired at the UTHSCD clinical site with data on the same set of subjects evaluated at DRI. Results will be used to assess factors such as instrument calibration and effects of training on test administrator performance. It is expected that over 500 different patients will be assessed (up to five times each) over 4 years during these studies. Results are expected to show that the computer-automated system can detect and quantify small but significant changes in function due to rehabilitation therapies and assistive devices, thereby objectively determining the efficacy of these interventions. Patients with different disabilities will be categorized by functional profiles. Thus, the progress of patients undergoing rehabilitation and monitoring by instrumented quantitative assessments can be judged against appropriate norms.

Quantification of Motor Performance: Muscle Strength and Endurance Testing

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Sponsor: National Institute of Handicapped Research

The project has developed three prototype isometric testing stations with stabilization to test 13 different muscle groups. Reliability testing has been completed on handgrip and elbow flexion. A study was completed comparing the effects of different types of pelvic and lower limb stabilization on the extent of pelvic movement during trunk strength testing.

A prototype of a portable myuodynamometer has been used in a clinical setting (Neuromuscular Disease Clinic at the University of Minnesota Hospitals). Sixty-three patients have had initial strength testing of five different muscle groups using this device. Clinicians are currently utilizing this information to map disease progress and to assist in the decision making process regarding therapeutic intervention decision.

Two surveys were completed regarding methodology currently being used for assessing spinal rom and strength.

Computerization of the quantification process has progressed during the past year. A software package

has been developed to sample force signals, display results in real time, direct the subject's actions by sounding tones, and store the results. A linkage with a data base management system (CLINFO) has also been developed.

Quantification of Mobility Performance for Functional Assessment, Diagnosis, and Therapy of Neuromuscular, Skeletal, and Synovial Joint Dysfunctions

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Sponsor: National Institute of Handicapped Research

Background—The 1983 Veterans Administration Rehabilitation Research and Development Progress Report outlined this comprehensive project—combining precise and rapid kinematic recording and analysis of abnormal gait with dynamic estimation of joint forces for the human lower extremities into a patient-specific musculoskeletal model of the pelvis, thigh, shank, and foot to establish the time-course and activity level of the individual muscles. Then presenting the relevant anatomical detail of the patient to the surgeon via computer graphics so that the surgeon could simulate a procedure, such as an osteotomy or tendon transplant. The computer system would then automatically alter the preoperative state of the musculoskeletal model to conform to the simulated change and show (again via computer graphics) the effect on the gait pattern of the subject. It is the direct analog of Computer-Aided Design (CAD), now so universally applied in simulating product to system design prior to manufacture.

The 1984 VA RR&D Progress Report updates the 1983 description.

Gait Analysis—Our Selspot I/TRACK system, now in routine use, is being adapted to the Selspot II Camera with four-fold improvement in translational and rotational kinematic resolution and accuracy, and with greater flexibility in the number of light emitting diode arrays versus sample frequency. Automated techniques for calibrating camera optics and electro-optical transducers have been developed. Feasibility studies for large-volume TRACK are underway to employ either moving cameras or multiple cameras to record movement over larger viewing volumes than the intersection of two fixed location cameras. Large-volume TRACK will place fewer restrictions on the movement trajectory of the patient.

Dynamic Joint Force Estimation—The NEWTON computer program automatically calculates joint forces and movements from TRACK kinematic data, force plate input, and body segment mass and inertial properties. We have developed computer programs which automatically calculate the patient-specific data, using as input computer tomographic scan data of human extremities. We are currently planning physical experiments on cadaver limb segments to compare direct measurement of the inertial tensor with our CT-based computer analyses.

The first pressure instrumented femoral head hemiarthrosis has been implanted into a consenting patient and we have accumulated much data—intraoperative, postoperative, through recovery and rehabilitation and most recently in normal gait. Local pressures correlated well with the high readings recorded here in vitro on cadaver specimens. Spatial integration of the pressure during gait, combined with TRACK/NEWTON data and analysis, will permit comparison of external estimation of force with direct internal measurement and illuminate the role of muscle co-contraction, not discernable from gait analysis.

Musculoskeletal Models—Our current hip/knee/ankle model has seven degrees of freedom and incorporates representations of 36 mono- and bi-articular muscles. We know (from prior studies using TRACK, NEWTON and then optimization analyses to predict individual muscle activity) that the model's greatest deficiency is the knee representation which has been thought of as a planar hinge. An explicit knee model is being generated based on experimental measurement, using an ultrasound technique of articular and menisci geometries and incorporating the passive restrains of the ligaments. When inserted into the overall model, including the 15 muscles which span the knee, the joint will have at least four degrees of freedom and will improve the accuracy of prediction of individual muscle activity. Reduction and interpretation of the human volunteer bone pin TRACK array data on knee kinematics has begun.

Computer Graphics Displays—The surgeon must be presented with a realistic, manipulable representation of the subject's anatomy as he undertakes the simulated surgery. The same CT data used for segment inertial property determination serve also as input to the anatomical representation. Progress has been made in automatic feature detection, so that, for

example, the computer automatically differentiates between hard and soft tissue in outlining for a detail such as the geometry of the condytes of the knee joint.

Much work has yet to be done but we expect to be able to automate to a large extent the delineation of the anatomical features from the CT data and thereby present color-graphics displays of patient anatomy.

We also are anticipating the more widespread use of NMR to avoid radiation exposure and we also are analyzing NMR scan data. Ultimately the same anatomical data will be used to scale and alter the musculoskeletal model to faithfully represent the specific patient's anatomy.

The computer vector graphics displays of patient movement preoperatively and subsequent to a simulated operation must be as realistic as feasible. Stick figure representation, for example, is not adequate to capture nuances of pathological and/or idiosyncratic movement. We have begun the development of display programs which represent the limb segments as articulated solid bodies, driven by the TRACK kinematic input■

Quantification of the Functional Capacity of Upper Limb Amputees

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Sponsor: National Institute of Handicapped Research

This project is intended to develop a technique for quantification and measurement of the upper-extremity functional capability of able-bodied and disabled persons. The technique being developed will use dynamic optimization theory to produce a single meaningful number derived from accessible measurements (such as myoelectric activity, speed, range of motion, etc.) and is intended to provide an essential link between measured performance and inferred functional capability.

An important aspect of dynamic optimization theory is that it yields a quantitative statement of the best way to perform a movement to accomplish the task modelled by the criterion function—subject to the limitations of the mechanical or biomechanical system performing the task. This ideal performance is then a benchmark for that task—that is, a yardstick against which other executions of that task may be compared. This is the key to the measurement technique: if a criterion function can be found which describes normal movement behavior, it is the natural quantitative measure of functional capability. It permits a disabled person's performance to be compared numerically to the "ideal" performance of an able-bodied person, and it defines the functional meaning of the comparison.

In previous work, dynamic optimization theory successfully predicted patterns of muscle activation of an able-bodied person maintaining one (carefully chosen) posture of the forearm against changing gravitational loads, thereby demonstrating the feasibility of the approach. In the past year, the mathematical technique has been refined, extended and improved. The major outcome has been the separation of the analysis into two separate components, one dealing with the static constraints of the nonlinear geometry of the musculoskeletal system, the other accounting for the dynamics of posture. The benefit of this separation is that realistic representations of the moving limb can be dealt with more simply. The analysis has been extended to provide a description of the maintenance of any posture of the forearm against changing loads. Extending the analysis to provide a description of the maintenance of any unconstrained posture of the upper extremity (arm, forearm, etc.) is presently under consideration.

Automatic Calibration Achieved—Work on the experimental verification and application of the mathematical technique is in progress. The most important requirement is a clean, high-fidelity measurement of myoelectric activity. An improved method of processing myoelectric activity is being developed. The processing technique is based on a mathematical model of surface myoelectric activity, from which the optimal (maximum likelihood) estimator of muscle force was derived. This optimal processor (which was previously implemented and tested using a laboratory-bound computer) has now been implemented using microprocessor technology, and this has yielded approximately an order of magnitude of improvement over conventional processing techniques. A major advantage of this digital microprocessor implementation is that the tedious but essential calibration process is performed automatically without user intervention. This is an important step towards making this new technology accessible on a turn-key basis to a clinical user with no specialized knowledge of computer programming■

Quantitative Evaluation of Nerve Repair

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Hypothesis—The lack of objective methods for assessing the extent of nerve injury or regeneration forces physicians to rely on subjective criteria in making clinical decisions and hampers the search for better methods of peripheral nerve repair. Similarly, better methods of nerve repair need to be developed because present methods, even those employing modern methods of microsurgical techniques, rarely result in full functional recovery.

We believe that regeneration can be quickly and reliably assessed by newly developed electrophysiologic methods which estimate the number and health of the axons crossing a focal lesion or repair site. In order to meaningfully enhance regeneration following injury, modern mechanical methods, including sutureless techniques, must be combined with pharmacological adjuncts that influence the rate and direction of regenerating axons.

Methods—Using computer-generated waveform simulations, we propose to characterize an electrophysiological assessment technique that generates a histogram indicating the distribution of added conduction delays (DAD) over a focus of injured or regenerated nerve. Following computer validation, we propose to test various assumptions regarding the DAD in a sequence of animal studies employing rats and primates in whom varying degrees of nerve injury have been surgically created. A newly developed system that magnetically measures the action currents generated by the passing wave of depolarization and repolarization potentially allows easier, more reliable recording of evoked potentials in these animals. These advances will be incorporated into software systems capable of being run on modern intraoperative assessment hardware. Simultaneously, we propose to study the effects of various adjuncts to nerve repair, including drugs that reduce scar formation at the repair site, agents that influence regeneration rates (nerve growth factors), and agents that suppress adverse effects of the immune response to regeneration.

Preliminary Findings

1. Distribution of added delays (DAD)—computer simulations indicate that by comparing various characteristics of two waveforms recorded from the same site well proximal to a local lesion (the first generated by supramaximal stimulation just proximal to the lesion, and the second stimulus delivered just distal to the lesion) a reasonable assessment of the proportion of axons crossing the site of injury and an estimate of their health can be derived.

2. Magnetic recordings—A number of animal studies demonstrate that the magnetically recorded action current is the magnetic analog of the electrically recorded compound action potential, and that standard assessment parameters such as conduction velocity, peak amplitude, etc., can be calculated from the magnetically recorded signal. The potential advantage of this method over standard electrical recording techniques is that the nerve is allowed to remain safe in its physiologic milieu during recording. Electrical recordings typically require the recording site to be suspended in air and thus endangers the nerve of dessicating under hot operating room lights.

3. Adjuncts to repair—We have partially analyzed the results of a primate model comparing the effects of tension at a nerve repair site. A significant gap (12mm) was created in the median and ulnar nerves. In one group (ES), the cut ends were approximated under tension with 8-0 sutures, in 2 other groups the gap was bridged intrafascicularly with autogenous nerve grafts using either 10-0 intrafascicular sutures (FS) or interfascicular hypoantigenic collagen tubes (FT). At 6 months postoperatively, electrophysiologic measurement of the proportion of proximal axons having regenerated across the site of repair or graft demonstrated the following:

ES (epineurial repair under tension)	—mean = 0.81 (range = 0.64–0.89)
FS (no tension/ graft)	—mean = 0.61 (range = 0.45–0.82)
FT (no tension/ graft/tube)	—mean = 0.56 (range = 0.40–0.71)

The slightly larger fraction of fibers crossing the epineurial suture repair done under tension indicates that some tension is not deleterious to regeneration.

Future Goals—Animal studies of other adjuncts are in progress as are refinements in magnetic recording techniques and further validation and implementation of the DAD analysis software■

Quantitative Measures for Assessing Therapeutic Effectiveness

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Sponsor: National Institute of Handicapped Research

This project has developed and built photoelectric modules that are used in a laser scanning system for tracking limb segment positions. A major effort was devoted to developing a calibration technique for the laser scanning system. A portable instrumentation package has been built which includes all the necessary signal processing for six channels of EMG and two footswitches, allowing interfacing with a PDP 11/34 computer. Some data collection on normal subjects has started.

Predictive Assessment in Prescription of Functional Aids for the Motor-Disabled

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Sponsor: National Institute of Handicapped Research

The goal of this project is to develop data and theory on which to base prediction of functional gain from technological intervention. It was proposed that this concept be applied to three handicapping conditions:

1. Disabling tremor of the upper extremities;
2. "Equinus" and other spastic gait abnormalities; and
3. Loss of vocal communication due to impaired articulatory motor control.

The motivation derives from the impracticality of exhaustive try-it-and-see assessment. As descriptive and predictive models of disabled human function are developed, they are hypothetically applicable to the clinical problem of streamlined assessment for optimal prescription.

Device Control-Interface Study

With respect to tremor, an initial study aimed at establishing the effect of three characteristics of device control interfaces on the accuracy of displayed movement, has been completed. The protocol required that the subjects perform discrete target acquisition and continuous pursuit tracking tasks in two dimensions on a computer-generated video display. They accomplished this by manipulation of either a conventional displacement-sensing joystick or one that rigidly sensed isometric force. The response signal was displayed directly, with low-pass filtering, or with integration providing control of cursor velocity. Data collected showed a significant improvement in signal-to-noise ratio and other measures of performance (for each of six adult neurology patients disabled by intention tremor) for at least one of the unconventional experimental conductions (force-sensing, filtering, or velocity control). While the combination of force-sensing and unfiltered velocity control was optimal for several subjects, it appears at this point that individual assessment will be clinically necessary. The number of subjects was insufficient to establish a correlation between etiology and optimal interface choice. The results were also consistent with earlier one-degree-of-freedom data showing isometric torque tremor to be invariant with respect to the voluntary tracking torque.

Spasticity-Damping Orthosis

The spastic gait project, active under past REC funding, was reactivated in the Fall of 1983. This work continues use of the wearable computer and interactive ankle orthosis simulator, that allows generation of energy-absorbing torque profiles across the ankle during gait. The objective is to extend the single-subject data already collected that show that the inappropriate ankle extension of equinus can be suppressed by a compliant brace applying a damping-like load during particular portions of the gait cycle. Experiments are now being conducted in the Newman Laboratory for Biomechanics and Human Rehabilitation at M.I.T.; these will use the TRACK system for collecting multi-segment gait data during trials with the orthosis simulator. Experiment-control software adjusts loading parameters as the subject walks, in order to minimize a simple cost function which measures the extent of abnormality. In effect, this lab system is the prototype of an automated prescription scheme. A simplified all-mechanical damping orthosis has been built for preliminary Activities of Daily Living (ADL) trials.

Work in the area of computer-guided assessment and prescription of non-vocal communication devices is presently very active, under the investigator's joint contract support from the National Institute of Neurological and Communicative Diseases and Stroke with Dr. Cheryl Goodenough-Trepagnier at Tufts-New England Medical Center. That scheme is based on predic-

tion of communication rates for candidate devices from motor assessment data as well as estimation of learning time and perceived benefit from evaluation of cognitive status and functional needs, respectively.

Investigation Regarding the Optimal Application of Technology-Based Treatment Modalities Applied to Assessing and Ameliorating Motor Defects

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The purpose of this study is to examine the role of cerebral and spinal contributions to motor control, and how they are influenced by therapeutic intervention. The rationale for the latter stems from the therapeutically relevant finding that specific pathways connecting supraspinal areas and spinal motoneurons can be strengthened by exercise and training.

The specific objectives are as follows:

1. To establish normative data from neurologically intact subjects.
2. To obtain data from hemiplegic patients previously treated in our program who are able to employ their involved extremity to perform the maneuvers necessary for conducting the test.
3. To correlate the presence of cerebral response EMG activity with the degree of motor recovery made by our previously treated patients, for the purpose of validating the degree to which our therapeutic intervention correlates with its presumed effect.
4. To obtain data from hemiplegic patients to determine whether the character of the cerebral response recorded on the intact side changes as a function of the degree of independence attained in performing ADL activities requiring use of the non-involved hand.
5. To correlate the electrophysiological measures obtained to standard measures of progress such as EMG gains, range-of-motion, and functional skills.

The Efficacy of Surgical and Rehabilitative Procedures of the Knee

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

This project is nearing the end of the third year. In order to test the efficacy of these procedures, a knee machine originally designed by P. C. McLeod was modified and used for this study. This machine measures in real time (with the aid of a desk top Apple IIe computer) nine functions of a cadaver knee specimen. These are: (1) flexion extension, (2) tibial rotation angle, (3) varus/valgus angulation, (4) anterior/posterior distance, (5) anterior/posterior force, (6) tibial rotational torque, (7) varus/valgus angulation torque, (8) body weight, and (9) quadriceps force.

Any of the above nine data channels may be used as a control channel at the convenience of the operator. The increments at which data are taken are also set by the operator; each time an increment of test input is achieved, all nine data channels are read and stored immediately by the computer and a high speed, 12-bit analog-to-digital converter. Once this information has been stored within the computer's memory, any two channels may be plotted graphically against each other, or the computer monitor, or an EPSON RX80 printer. Also, a complete data listing may be displayed on the printer or the data may be stored on a 5¼ inch floppy disk and examined at the leisure of the orthopaedic surgeon. It is important to note that since the data from the knee test are obtained in essentially real time any of the nine parameters may be plotted against any other to give realistic data of interactive motion and force from a given test set. All of the necessary software is provided for knee testing, graphics, and data storage and listing. The software is menu-driven and is very user-friendly.

In a knee testing apparatus modified for this project, the ankle at the lower end of the tibia will move vertically a total travel of 18 inches. Body weight is applied up through the ankle and is automatically controlled, once preset by the operator. The control near the top of the right-hand panel will cause the hip and ankle to rotate 360 degrees in synchronism about a vertical axis through the hip and ankle so that the specimen may be operated on or X-rayed from any direction. The lower control on the side panel is the input of a remote master-slave hydraulic system to change the quad

length which in turn controls flexion/extension. The other two controls on the ankle provide tibial rotation and varus/valgus angulation. Either or both of these controls may be used as input or may be very quickly (without the need for tools) disconnected so that the knee is free to follow its own natural geometry throughout a test. However, the angular motion of the tibia in both transverse and coronal planes is monitored even though the force mechanism has been disengaged.

A typical tibial rotational versus torque plot may be viewed either on the monitor or the RX80 printer for a permanent record.

To date, six papers have evolved from this study and four are being reviewed at this writing■

Epidemiology of Physical Activity

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

During the next year, we will continue our data collection and analysis of previously collected data designed to evaluate the Large-Scale Integrated (LSI) activity monitor as an objective measure of physical activity for epidemiologic research. The focus of the upcoming year will be to complete the requirements of the grant in addition to expanding into new areas of physical activity research. Specifically, we have completed the first phase of the research; 48 college students have worn various activity devices including the LSI. We will analyze these data during the next 2 months.

Thirty postal carriers have been recruited, and by November 15 they will have completed the first seasonal assessment of activity. We plan to obtain the winter measurements in January. We have modified the LSI monitors for assessing activity in spinal cord injured patients. The population is available, and in November this phase of the project will begin. The industrial group has been identified; however, participants have not yet been identified. This phase will not begin until January 1.

We plan to expand our research efforts by including two new methods of physical activity evaluation as well as an additional population. The two methods of assessment will include a new survey which is being employed in the MONACA study in Europe. We have special permission to test the survey. The second measurement will be a new type of monitor which has been developed in Wisconsin. These instruments will be available within the next 2 months. We also plan to expand the evaluation of activity into our clinical trial of activity in postmenopausal women (RO 1 AM 21190). Dr. LaPorte is co-principal investigator of this project■

[See also **II. Orthotics, B. Upper Limb**, Assessment of Hand Function and the Development of Wrist-Hand Orthoses; **VI. Biomechanics, C. Human Locomotion and Gait Training**, Evaluation of Methods to Measure Locomotion Performance and Activity; **VIII. Properties of Muscle**, Myoelectric Assessment of Human Lumbar Muscle Function, Muscle Fatigue Differences Due to Handedness and Gender, the Muscle Fatigue Monitor, and The Estimation of Muscle Fiber Conduction Velocity]

VI. Biomechanics

A. Joint Studies

1. General

Joint Contracture: Biomechanical-Clinical Correlates

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Sponsor: National Institutes of Health
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Current evidence suggests that stress-deprivation effects on soft tissues are profound and occur rapidly and that recovery from stress deprivation is quite slow. In this respect, recovery seems to parallel the effects of exercise on normal connective tissue. For example, our studies indicate that a large effort over a long period of time is required for a small hypertrophy increment of tendons or ligaments. The purpose of the proposed research program is to document further: (i) the fibrous connective tissue morphological and molecular changes resulting from stress deprivation, and (ii) the consequent alteration in physical characteristics. The answers to these questions are particularly important with respect to the development of the rationale for treatment and rehabilitation of soft tissue injuries, such as the knee ligaments.

A standard internal fixation model is used to induce stress-deprivation effects in rabbit knees. Capsular and ligamentous structures from the model are characterized by biomechanical, morphological, biochemical, and metabolic techniques on a progressive time base during the development of and recovery from the stress-deprivation state. Hormone or drug treatment effects are also evaluated for efficacy in modulating the development of and recovery from the stress-deprivation state.

Biochemical analyses employed permit evaluation of collagen turnover, total proteoglycans, and collagen cross-link quantitation (reducible and nonreducible). Light microscopy and transmission EM are also used to characterize matrix and cells as well as the ligament insertion sites. Biomechanical tests on ultimate strength and stiffness of bone-ligament-bone complex as well as the mechanical properties of the ligament substance are performed. In addition, arthrographic characterization of contracture strength is assessed.

Biomechanics of Ligament/Tendon Repairs and Grafts

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Sponsor: National Institutes of Health
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It is our hypothesis that healing of ligaments and tendons is a long-term process that involves a return in strength due to callus formation followed by long-term remodeling of the collagen, involving changes in fiber alignment, ground substance, and cross-linking. We further hypothesize that the extent to which a blood supply is available has a significant effect on the return in strength. Repairs in relatively vascular regions and free grafts need protection for prolonged periods of time. On the other hand, the presence of a profuse vascular supply may permit a more rapid return in strength, allowing earlier motion, earlier rehabilitation, and return to normal activity with less disuse effects.

To test these hypotheses, we will measure the return in strength and biochemical remodeling over time of selected primary repairs and grafts in activity conditioned, skeletally mature beagles. The following specific situations will be studied.

Primary Repairs—(i) We will compare flexor-tendon repairs in highly vascular paratenon regions with repairs in the synovial sheath, a comparatively avascular region. (ii) An anterior cruciate mid-substance partial injury will be studied with and without the use of a fat pad sutured to the ligament to provide an additional source of blood supply. (iii) Healing in the medical collateral ligament will be determined for complete mid-substance tears induced at the time of surgery.

Grafts—(i) A bone-lateral tendon-bone free graft substitute for the anterior cruciate ligament will be compared with the same graft that incorporates a tissue flap that provides its blood supply. (ii) A flexor tendon autograft will be compared with an allograft.

In the first year, we will document the local blood

supply using microangiography and refine the surgical techniques, particularly to avoid interruption of the blood supply. We will also verify our existing gripping methods for mechanical testing of the isolated tendons. During the second and third years of the project, we will measure both the return in strength and the biochemical changes in each model.

2. Lower Limb

Evaluation of Joint Loading in the Use of Walking Aids in Total Hip Replacement Patients

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Sponsor: University of Strathclyde

Abstract—The immediate result of total hip replacement surgery is a low-friction joint with acetabular and femoral components rigidly fixed in the pelvic and femoral bones respectively. However, soft tissue damage results in reduced abductor function as well as a general tightness surrounding the hip joint.

Postoperative care is a compromise; protection against subluxation of the joint and tearing of the abductor attachments versus the need to load the joint to reduce stiffness and bone and tissue atrophy. Surgeons vary in their prescription of therapy and walking aids (which range from walking frames to elbow crutches to stick). Some patients are encouraged to leave the hospital in 2 weeks with no aids, while it is recommended that others use at least one stick up to 6 months postoperatively.

The purpose of this study is to obtain biomechanical parameters of aided gait that can be considered when prescribing an aid and it use, in order to optimize patient mobility and joint protection.

The types of aids being studied are elbow crutches and walking sticks. Besides the type of aid, the technique used to measure for the length of the aid is being evaluated.

The analysis focuses on both the upper and lower limbs. The shafts of the aids are strain-gauged for determination of three forces. Particular attention is given to the loading of the shoulder girdle by combining the kinetics of the aid with the kinematics of the upper limb. The cuffs of the elbow crutches are also gauged to evaluate the contribution of the cuff in supporting the patient. The lower limb ground-reaction force is measured to assess the weightbearing relief which the aid is allowing. Other gait parameters such as stride length, velocity, and the duty cycle of the aid during the gait cycle, are measured as indicators of mobility.

Ankle Biomechanics

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Sponsor: University of Strathclyde

Abstract—A computer model of the ankle system has been formulated which is based on a single, free-rolling bearing joint, with four muscle groups (giving nine muscles in all), and moments about two axes (producing plantar/dorsi flexion or inversion/eversion). The Strathclyde TV Gait Analysis System is used for the collection of data.

Data from patients suffering from hallux valgus were chosen to be tested with this model, as this condition is likely to have a great influence on the ankle dynamics.

Since hallux valgus is a common condition, various surgical procedures have been developed and used for its correction. Four of these procedures have been chosen for study (Keller's resection, Wilson's osteotomy, IMTP fusion, and sylastic prosthesis), before and after undergoing surgery.

Results should provide a better understanding of how patients with hallux valgus place their feet during walking and how this affects the ankle dynamics and leg-muscle forces. By analyzing data from patients undergoing the above four surgical procedures, the effectiveness of such treatments can be compared more quantitatively and objectively.

Clinical Biomechanics of the Knee: Rotation Laxities

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Sponsor: National Institutes of Health
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This project is directed at three major goals: (i) determining the function of knee ligaments in limiting internal/external rotations of the leg, (ii) improving the accuracy of diagnosing ligament injury associated with rotatory instabilities, and (iii) determining the appropriate attachment points and initial tension for biological grafts and prosthetic ligaments used to replace the cruciate ligaments.

Our methods employ a complete three-dimensional six degrees of freedom analysis of joint loads and motions. Four major projects will be conducted.

Ligament Restraints—The forces and moments developed by the ligaments in resisting internal and external tibia rotations will be measured. The effect of changing the location of the rotation axis will be investigated.

Clinical Examinations—We will measure, in cadavers, the effect of simulated ligament injuries two ways: by the increases in three-dimensional joint laxity under known loads and by changes in knee kinematics during each of the major clinical examinations used to diagnose injury. To apply our results to patients, a laxity examination table will be constructed incorporating an instrumented spatial linkage for measuring three-dimensional joint motions and transducers for measuring the force applied during the examination. The errors associated with skin mounting will be studied in cadavers, and a group of normal patients will be evaluated for anterior-posterior, internal-external, and abduction-adduction laxities.

Surgical Reconstruction—The total anterior-posterior laxity of intact cadaveric knees will be measured as a function of flexion angle and internal-external tibial rotation. The anterior cruciate ligament will be removed and the change in laxity recorded. Grafts will be implanted, varying the tibial and femoral attachments, the initial tension, and the flexion angle when tension is applied. Laxity surfaces will be compared to determine the conditions that best reproduce the intact knee.

Knee Modeling—Collaboration will continue with researchers at Ecole Polytechnique in Montreal, Canada, who are developing a finite element model of the knee with support from the Natural Sciences and Engineering Research Council of Canada. This study will provide experimental data on the mechanical properties of ligaments required by the model. At the end of the first year, the model will be implemented on our computers. The model will be validated and used to investigate instabilities under activity conditions■

Ligamentous Knee Stability: Combined Clinical Loadings

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

Ligamentous stability of the knee will be quantified in vivo and in vitro by (i) direct measurement of force versus displacement responses for anterior-posterior tibial drawer, (ii) moment versus rotation responses for varus-valgus angulation of the tibia, and (iii) torque versus rotation responses for internal and external rotation of the tibia. The stiffness and laxity data collected will quantify the contributions of knee ligaments to overall stability of the joint and help to improve the accuracy and interpretation of the clinical knee laxity exam. Existing test fixtures will be modified to study the complex responses of cadaveric knees to combined loading states on a MTS materials test machine, including the application of tibial-femoral contact force (joint load). The effects of knee ligament section and total knee replacement will be examined with this advanced methodology.

The UCLA clinical knee-testing apparatus will be modified to include measurement of anteromedial and anterolateral rotatory instabilities. Patients with injuries to their knees will be tested before and after their surgical reconstructive procedures to permit an objective assessment of their operative results. Patients who have received total knee replacements will undergo selected testing to evaluate the stability of their implants in situ.

A portable field testing apparatus will be designed and prototypes constructed for use in the UCLA clinics and Sports Medicine Center. These units will

expand our data collection capabilities and allow screening studies of varsity athletes prior to the competitive season in order to study correlations of knee stiffness and laxity with the incidence and severity of knee injury.

Pathokinesiology of Anterior Cruciate Ligament Deficiency

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Introduction—Rotational instability of the knee joint following rupture of the anterior cruciate ligament is recognized by many orthopaedists as a major problem in the active individual. In many persons, absence of this ligament leads to progressive instability, functional disability, and knee joint deterioration. To prevent this sequence of events, numerous technical solutions, including repair and/or reconstruction of the anterior cruciate ligament, and rehabilitative strengthening have been proposed. However, a significant percentage of patients with an absent anterior cruciate ligament have no functional disability and little or no objective instability. In these individuals, progressive instability and knee joint deterioration do not seem to occur.

The obvious discrepancy in the clinical course of patients raises multiple questions regarding the nature of the knee with an absent anterior cruciate ligament and the appropriate treatment for this deficiency. A major problem for the orthopaedist in attempting to evaluate the multiple alternatives available is an incomplete knowledge of the biomechanical alterations of the knee joint produced by an anterior cruciate ligament tear. In addition, little is known about the response of the patient to these alterations in order to compensate for this injury. Documentation of instability has been largely clinical in nature, based upon nonfunctional evaluations and using inexact descriptive tools. The inability to precisely describe the deficit involved has made evaluation of treatment modalities even more difficult.

Objectives—The objectives of this project are to define the knee kinematics and kinesiology in normal individuals and in the functionally compromised and functionally able patients with anterior cruciate ligament deficiency. The testing tasks are level walking, pivoting, and controlled exercising using gait analysis and isokinetic techniques. Information is collected using electromyography and total knee goniometry. This information is then subjected to extensive computer analysis to define abnormal motions, dissimilar synergy patterns, and abnormal variations in torque production that occur among the injured and uninjured groups.

By comparing these groups, compensatory mechanics might be identified that could influence the choice of surgical procedure, orthotic device, or exercise program. The analytic techniques could then be carried beyond the level of clinical investigative tools to an invaluable diagnostic, prognostic, and evaluative system for the anterior cruciate ligament deficient knee.

General Aims—The work plan will establish:

1. The kinesiology of the knee joint in terms of translational and rotational motions, the muscular synergies, and general body motion in two functional activities, level walking and pivoting;
2. The translational and rotational motions in two controlled conditions, internal-external rotation and flexion-extension.

The purpose of the controlled conditions is to stress the knee through its full range of motions since functional activities utilize only a portion of the full range. The following populations are being studied:

1. Patients with functional disability secondary to chronic anterolateral rotatory instability;
2. Patients with documented anterior cruciate ligament deficiency, but no functional disability;
3. Normal persons with no injury history.

Methodology for Knee Kinematics Measurement—Subjects are asked to:

1. Walk straight at free and fast speeds;
2. Walk straight and make a 90 degrees pivotal turn as they normally would at a speed of one meter per second;
3. Walk straight and make a 90 degrees pivotal turn and keep the pivoting foot planted (do not rotate over heel) at a speed of one meter per second.

Knee kinematics are measured using a 6 degrees of freedom goniometer and are acquired in real-time with a PDP11/03 computer sampling at 25 samples per second. Instantaneous and global screw motions are calculated; the reference posture for the global screw motion is the anatomic standing position.

Results—The anatomic and screw motions of ten uninjured and five injured people have been studied. The anatomic motions of all subjects were very similar. The measure that concentrates upon and demonstrates differences in kinematics is the instantaneous screw motion. The screw motions of uninjured knees and tight injured knees are remarkably similar to straight walking. However, during pivoting there are some major differences. The instantaneous screw motions of loose injured knees differ from those of uninjured knees during all four tasks■

Biomechanics of the Hip and Knee

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

Specific Aims

1. To investigate the effects of incorporating fiber length, fiber direction, and fiber type into our existing muscle model.
2. To investigate the effects of differing cost functions on muscle force predictions and to study the appropriateness of using differing cost functions for differing activities in normal subjects and in subjects with selected abnormal conditions.
3. To investigate, in a comprehensive manner, effects of varus, valgus displacement, and rotational proximal femoral osteotomies on three-dimensional hip joint forces.
4. To study the three-dimensional loads on the hip and knee during straight-knee lifting of a 20-pound load from the floor, bent-knee lifting of a 20-pound and 50-pound loads from the floor, jogging, tennis serve, and golf swing.

Objectives (Correlated to the Four Specific Aims)

1. We anticipate that this aim will be completed by the end of 1984.
2. We expect to complete all of the studies on optimization criteria within the first few months of the coming budget year as most of the groundwork is completed as described above. The remaining portion of this aim to be accomplished is to determine how pathological conditions affect the choice of optimization criteria. For this portion, we must collect data on a variety of subjects with pathological conditions (i.e., painful gaits, joint fusions, neurological deficits). This data will be collected in the coming budget year when the new Vicon system is operational. Once collected, the data will be input into our current programs and then we will determine the appropriateness of the various criteria based on simultaneously collected EMG data.
3. This work is completed as originally planned. We are considering the possibility of extending our work to take into account the alterations in the location of the knee center which can occur with the osteotomies.
4. Data for the final specific aim will be collected, analyzed, and reported within the coming budget year. We will select only one or two optimization criteria for the work, and the choices will be based on the sensitivity studies described above■

Mechanics of Human Acetabulum

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The objective of this study for the coming year is to better elucidate the stress fields in the acetabulum and tibial plateau before and after joint arthroplasty. The goal is to better understand the normal joint mechanics and to better evaluate and design artifical components.

Considerations will be given both to conventional cemented components and to new porous ingrowth components. Our methods will incorporate plane strain and equivalent thickness finite element models that will be implemented in such a manner as to make the evolution to future three-dimensional models a smooth transition. Some of our models will use a contact element approach in an effort to better stimulate in vivo loading.

The studies will parametrically examine the influence of geometry and materials. Special emphasis will be directed toward maintaining normal bone stresses and avoiding poor stress transfer characteristics at the component interfaces■

Biomechanics of Anterior Cruciate Repairs

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Sponsor: National Institutes of Health
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The goal of the proposed research is to better understand the mechanical factors in surgical repair procedures for chronic anterolateral insufficiency of the knee, where the repair requires an anterior cruciate substitute to be established. Experiments will be run on cadaveric knee specimens. Ligament forces will be measured by buckle force transducers on the four major knee ligaments. A six degrees of freedom goniometer system will be used to measure three-dimensional knee motion when the knee is subjected to a wide variety of external load directions.

Normal knees, knees with a simulated anterolateral injury, and knees repaired by one of eight procedures will be tested in an identical manner. Theoretical ligament lengths, and hence, loaded ligament states, will be predicted using already developed theoretical knee models with the measured three-dimensional motion as input. The influence of repair insertion location will be studied both theoretically and experimentally. The normal and repaired knees will be compared on the basis of anterior cruciate or substitute force magnitude, joint laxity, and load sharing by the other ligaments■

In the upcoming funding year, our experiments on the constitutive behavior of chondroepiphysis will continue, using a simple linearly viscoelastic approximation of biphasic material behavior developed during the previous year. Axial compression tests of newly ossified trabecular bone specimens are expected to begin early in the upcoming year, as are axial tensions tests of cortical bone specimens from the proximal diaphysis and neck. We plan a series of bench tests to further explore the efficacy of Prescale film as a substitute for piezoresistive transducers for the human contact pressure measurements. Work on developing a semiautomated finite element mesh generating scheme will be continued, to be followed by a dry run of the full three-dimensional stress analysis problem. Intensified efforts will be focused on the problem of obtaining more human autopsy specimens.

By the end of the upcoming year, we hope to be into the early production phase of collecting constitutive data and performance stress analyses on several of these final human specimens■

[See also **II. Orthotics, A. Lower Limb,** Design and Evaluation of a Knee Orthosis; **III. Total Joint Replacement and other Orthopaedic Implants, B. Hip,** Biomechanical Assessment of Patients Treated by Joint Surgery, Quantitative Analysis of the Effect of Total Hip Arthroplasty on Stress and Strain in the Human Pelvis, The Efficacy of Radiolucent Low-Modulus, Total Hip Surface Replacement, and Total Hip Implant Biotelemetry; **C. Knee,** Interaction of Total-Knee Replacement Geometry with Knee Ligaments, Investigation of a Simplified Internal Knee Prosthesis, In Vivo Loading on Total Knee Joints, and Biomechanical Study of Total Knee Replacement]

Proximal Femur Load Transmission in Early Childhood

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Sponsor: National Institutes of Health
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In spite of the extensive clinical resources devoted to management of hip disorders in children, there is an almost total absence of quantitative data regarding the mechanical structural behavior of the juvenile femur. We propose to conduct a detailed engineering investigation of the load transmission through the proximal femurs of normal children, ages 1 through 7 years.

3. Upper Limb

Functional Forces in Normal and Abnormal Fingers

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This research project will study five problems related to functional forces in normal and abnormal hands: (i) ligament force analysis of finger and thumb MCP joints, (ii) pathologic force simulation investigating tendon, nerve, and joint injuries, (iii) intrinsic muscle distribution, (iv) in vivo tendon testing, and (v) hand patient functional evaluations.

Our specific aim will be to complete analysis of ligament contributions, both theoretical and experimental, to analyze hand joint stability, and to calculate intrinsic muscle force response to static loading. We will validate flexor and extensor tendon forces by in vivo buckle transducer studies. We will then apply our normative model to pathologic hand involvement of nerve, tendon, and joint problems. Finally, we will integrate this information with the clinical setting to obtain a hand function index to evaluate preoperative and postoperative joint arthroplasties, tendon transfers, and ligament reconstructive procedures. Ligament stiffness contributions to MCP joint stability have been initiated and will be completed this year.

The methods involve applying ligament anatomic and strength data to perform an equipollent force analysis to distribute the resultant force among the ligament components and joint articular surfaces. The contact area of the joint surfaces under load will be further studied using cartilage staining techniques. Pathologic force resulting from rheumatoid hand deformities, tendon lacerations, and peripheral nerve injuries will be simulated in our tendon model to predict resultant hand deformities and function loss, and the results compared with in vitro and in vivo studies of subjects with joint subluxations, muscle weakness, and tendon malfunction. Hand functional strength assessment in neuropathic conditions will be completed. In vivo tendon forces will be measured in patients with carpal tunnel syndrome or tendon transfers. With a strain-gauge instrumented pinch meter, the applied finger/thumb force will be compared with directly measured tendon force (buckle transducer). Finally, functional hand evaluations will combine motion, strength, dexterity, and daily activity analysis to establish a Hand Performance Index.

The results will compare a normal subject population with preoperative and postoperative individual patient assessments, and the results will be distributed to clinicians.

Static Force and Stability Analysis of the Human Elbow

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The objectives of this project are: (i) calculation of the muscle and joint forces of the elbow joint under static and dynamic conditons; (ii) verification of the theoretical results by using quantitative electromyographic measurements as well as function strength evaluation; (iii) examination of the role of ligaments and articular surfaces in elbow joint stability; and (iv) biomechanical evaluations of surgical procedures and prosthesis replacement for treatment of the elbow joint.

A normative model of the muscles and ligaments around the elbow joint has been established. This model will be used to calculate the muscle and joint forces under static and dynamic conditions. An optimization method based on newly designed objective criteria will be used for solution of the indeterminate problem. The estimated length and tension relationship of each muscle across the elbow joint will be implemented in the model for muscle force calculation.

Results of quantitative electromyographic (EMG) experiments have been obtained. The application of these EMG data for muscle force calculation will be performed and compared with those of the theoretical calculations. The contribution of ligaments and articulating surfaces to elbow joint stability under static conditions will be studied by using stiffness and laxity tests. Joint contact areas under load will also be examined.

Finally, various designs for joint replacement will be assessed using bench tests as well as patient functional performance.

Biomechanics of the Wrist

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Wrist Kinematics—The objective of this proposal remains the characterization of motion in the rheumatoid wrist and in the surgically reconstructed wrist. We intend to accomplish in the next year these specific aims: (i) complete the statistical comparison of the kinematic variables in three study groups (15 normal wrists, 18 rheumatoid wrists, and 7 postoperative Swanson wrist implants) and (ii) complete the correlation of radiographic indices and kinematic variables in 18 rheumatoid wrists. The motion is determined by the use of a three-dimensional sonic digitizer. Spark gap arrays are secured to the forearm and hand. Orthogonal, oblique radiographs are taken of the extremity with the spark gaps in place. The patient is positioned in the sonic digitizer field and completes a prescribed series of motions. The motion is described by the specification of the location and orientation of the corresponding screw displacement axis (SDA) about which the hand moves relative to the forearm. Radiographic indices are calculated from PA views of the wrist. Indices include carpal height ratios and carpal translation.

Wrist Kinetics—The objective of this proposal remains the measurement of moments, torques, and angles of twist in the total wrist prostheses in cadaveric arms, in normal undiseased wrists, in rheumatoid wrists, and in surgically reconstructed wrists. We intend to accomplish in the next year these specific aims: (i) initiate in humans the measurement of moments in normal, unoperated rheumatoid and surgically reconstructed rheumatoid wrists and (ii) initiate in cadaveric wrists the measure of moments, torques, and angles of twist effected by a commonly used tendon transfer in rheumatoid wrist reconstruction, the ECRL to ECU transfer.

The moments are determined by securely mounting a cadaveric forearm with six transfixing Steinmann pins in an experimental apparatus. Sequentially, the six prime wrist movers are loaded with a 4-kg mass. The induced moments about the wrist are transmitted by a rod mechanically attached to the hand to a configuration of load cells. The resulting load cell's output voltages are recorded. The experimental apparatus is also designed for the in vivo studies, but will require adaption for arm immobolization and rod attachment■

Biomechanical Study of the Radial-Ulnar-Carpal Joint

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During the next year of support, the primary scientific goal of this investigation into the anatomy and function of the radial-ulnar-carpal joint is to continue to measure the forces and pressures on the radius and ulna for intact and surgically modified wrists. The pressures between the distal radius and ulna also will be measured using our current methodology. Cadaveric forearms mounted in a frame will be loaded via the wrist flexors and extensors, with the forces on the radius and ulna being measured by load cells attached to those bones. The pressures at the articulating joints will be recorded on pressure-sensitive film. These force and pressure measurements will show us in vitro the consequences of various surgical procedures for the distal radial-ulnar-carpal joint.

Five surgical procedures will be examined this coming year. In the first two procedures (lengthening and shortening of the ulna and partial excision of the articular disc of the triangular fibrocartilage complex), only the pressures between the distal radius and ulna will be examined, as the radial-ulnar-carpal joint force and pressure measurements will have been completed.

The effects of three other surgical procedures on the force and pressure measurements on both the radial-ulnar-carpal joint and the distal radial-ulnar joint will be examined. These procedures are: (i) carpal ligament divisions (scapholunate, scaphotrapezial-trapezoidal, lunotiquetral), (ii) carpal malalignments (dorsal intercalated segment instability, palmar intercalated segment instability), and (iii) ulnar-carpal translocations. Two additional procedures: carpal excisions (scaphoid, lunate, triquetrum); and, intracarpal fusions (scaphotrapezial-trapezoidal, scascapholunate, lunotriquetral, triquetrohamate) will be started during the following year■

[See also **VI. Biomechanics, D. Upper Limb Function**, Processes Underlying Arm Trajectory Formation]

B. Spine

The Role of Abdominal Muscles in Stabilizing the Spine in Flexion: the Mechanics of Force Transmission

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Sponsor: University of Strathclyde

For many years it has been accepted that the principal function of the thoracolumbar fascia (TLF) has been to form an origin for the muscles of the abdominal wall, and thus to provide a firm anchorage from which they act to compress the abdomen. It has been argued that the resulting increase in intra-abdominal pressure (IAP) can reduce both the bending and axial loads on the vertebral column. In the past decade, the work of Farfan and others has recognized the potential for an additional mechanism by which the TLF may stabilize the lumbar spine. For example, Fairbank and O'Brien demonstrated that when the fascial sheet is subjected to lateral tension it extends the spine. In so doing it will, of necessity, increase the compressive, axial force on the spine. Although they involve the same tissue structures, the two supporting mechanisms outlined above conflict biomechanically. We have investigated this problem by several different methods.

In contrast to the large number of investigations on IAP, very little has been published on the mechanical characteristics of the TLF. Uniaxial and biaxial tensile testing of samples of the posterior layer of the TLF have been carried out in a physiological environment using optical extensometry. Polarizing light microscopy has been employed, in conjunction with a loading device, to quantify the change in structure of the fascia under load.

Whole cadaver studies are underway to measure the sagittal movements of the lumbar spine in a simulated lifting posture—this involves fixed hips and the spine flexed to the point where it is supported solely by the ligamentous structures (similar to in vivo conditions in which it has been shown that the paraspinal muscles are inactive). In this study, three rubber balloons are positioned along the length of the abdominal cavity. The central balloon is constrained internally in an axial direction so that when inflated in isolation it develops tension in the muscles of the abdominal wall alone. When the outer two balloons are also inflated to the same pressure additional forces are developed on the diaphragm and pelvic floor, thus simulating a raised IAP. The central balloon is designed so that it can deflate while leaving the outer balloons acting on the diaphragm and pelvic floor. Thus, the two supportive mechanisms ascribed to tension in the abdominal muscles in vivo can be simulated in isolation and in concert.

Uniaxial tests revealed that the TLF is approximately twice as stiff as has been previously suggested, and constrained biaxial tests yield corresponding results. Combined microscopic and mechanical examination indicate that the net-like structure of the posterior layer of the TLF is not highly mobile. The cadaveric studies displayed similarly high stiffness within the fascial layer, yet its influence on the sagittal movement of the vertebral column was noticeable.

The Detailed Anatomy of the Vertebral Attachments of the Thoracolumbar Fascia and Its Functional Implications

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In 1980 Fairbank and O'Brien suggested that there was an interaction between the thoracolumbar fascia (TLF) and the posterior vertebral ligaments of the lumbar spine. Tension in the TLF due to abdominal muscle action could be transmitted to the ligaments causing them to deviate laterally and thus produce an axial contraction. In this way, abdominal muscle contraction could be converted to tension in the ligaments which will stabilize the lumbar spine (e.g., in lifting maneuvers). In view of the current confusion in the anatomical literature we have made a detailed study of the TLF and its connections that underlie these important biomechanical implications.

Dissections of the lumbar region were made of four fresh and four embalmed cadavers. Special attention

was paid to the posterior layer of the TLF, the junction of the posterior layer with the supraspinous and interspinous ligaments, and the attachments of the middle layer of the fascia to the transverse processes. Computerized tomography (CT) was used on volunteers to clarify the spatial relationship between the TLF and the ligamentous structures in the lumbar spine in standing and flexed positions and during the valsalva maneuver. Conventional histological techniques were used to examine the laminar structure of the posterior layer of the TLF and the attachments of the fascia to the vertebral ligaments and the transverse processes of the vertebrae. The tissue interface between the posterior layer of the TLF and the ligaments was also treated with a modification of Masson's Trichome stain, to identify tissue fibers under tension. This showed the load transmission pathways in the connective tissue components under conditions simulating flexion, abdominal muscle action, and their combination.

The results of these investigations have confirmed and clarified anatomical features previously published. In addition, some new findings were made which could have significant functional implications. The CT scans revealed that, rather than lying in the coronal plane, the posterior layer of the TLF, on leaving the midline, is directed posteriolaterally, even in full flexion. The deep lamina of the posterior layer of the TLF blends with the interspinous ligament in the sagittal plane. Although this attachment does not enable the fascia to pull laterally upon and thus open the bifid interspinous ligament, it may still generate tension in the ligamentous fibers. In addition, the supraspinous ligament may also be put under tension as it is enveloped and pulled posteriorly by the outer two laminae of the fascial layer. The middle layer is attached to the transverse processes of the lumbar vertebrae and the intervening intertransverse ligaments. These ligaments are thin and membranous with no obvious fiber arrangement, and they extend to the base of the transverse processes. In contrast, the attachments to the tips of the transverse processes are thickened and consist of converging fiber bundles. This fiber arrangement is ideally suited to enhance stability in the coronal plane as a result of abdominal muscle action■

Mechanical Analysis of Cervical Spine Stabilization Techniques

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Little information is currently available about the efficacy of techniques for internal stabilization of the cervical spine. The objective of this study was to develop a methodology for analysis of spinal motion with controlled loading and to apply this methodology to two types of cervical spine stabilization, interspinous wiring and a segmental wiring technique.

Materials and Methods—Four intact human cervical spines (C1 to T1) were obtained from fresh donated cadavers and frozen prior to use. Each spine was stripped of surrounding musculature, but all ligaments and joints were carefully preserved.

For testing, each specimen was thawed to room temperature, and C1 through C3 vertebrae were embedded in resin for mounting. Forces were applied via a 12 cm moment arm to a loading fixture on T1. Utilizing four heavy Steinmann pins, a 6 degrees of freedom motion transducer was affixed to the bodies of C5 and C6. The instrumented spine was mounted on a servohydraulic testing machine (MTS). Analog outputs were fed to a data acquisition and analysis system (HP). Computer programs were written to generate force-displacement curves.

Each spine was tested under loading conditions that produced axial rotation, lateral bending, and flexion-extension as the primary motions. Coupled motions were allowed to occur as they would in vivo.

Following intact testing, a flexion-distraction disruption at C5-C6 (in our experience the most common) was produced by cutting the disc and all ligaments except the anterior longitudinal ligament. The spine was then retested following stabilization with each of two methods: (i) interspinous wiring between C5 and C6, using 20 gauge stainless steel wire; and (ii) segmental stabilization from C4 through C7, achieved by wiring the laminae at each level to a U-shaped 6.4 mm diameter stainless steel rod.

Force displacement data were used to calculate the stiffness at O force (newtons/degree of angular displacement) for each of the primary rotations of the spine in the intact and both disrupted, then stabilized, situations.

Results—Stiffness results are presented in Table 1. Using the student T test, the intact spine was significantly stiffer in axial rotation than in flexion-extension ($p=.05$) or lateral bending ($p=.04$); and in lateral bending was significantly stiffer than in flexion-extension ($p=.04$).

TABLE 1

Rotation	Mean Stiffness N/Deg.		
	Intact	I S Wire	U Rod
Axial	4.8 (1.8)*	2.6 (1.4)	3.0 (1.5)
Flex-Ext.	0.54 (0.16)	2.1 (0.8)	17.0 (17)
Lat. Bend	1.4 (0.41)	0.73 (0.11)	0.60 (0.46)

The disrupted spine fixed with interspinous wiring was significantly stiffer that the intact spine in flexion-extension ($p=.02$), but significantly less stiff in axial rotation ($p=.03$) and lateral bending ($p=.04$). The disrupted spine fixed with segmental wiring was not significantly different in any rotation from the intact spine.

We also looked at the total angular excursion that occurred between +5 newtons and −5 newtons of applied force. These results are presented in Table 2. For the intact spine, displacement was significantly greater in flexion-extension than in axial rotation ($p=.03$) or lateral bending ($p=.02$). Differences in excursion between the intact spine and the disrupted, fixed spine (for either type of fixation) were probably not significant for axial rotation and lateral bending. For flexion-extension, the decrease in excursion allowed by the U rod as compared to the intact (one-sixth) was highly significant ($p=.001$) and the decrease in excursion allowed by interspinous wiring as compared to intact (one-half) was significant ($p=.01$).

TABLE 2

Rotation	Mean Angular Excursion (+5 N.)		
	Intact	I S Wire	U Rod
Axial	2.5 (1.0)*	3.6 (1.8)	2.8 (1.4)
Flex-Ext.	6.6 (0.9)	3.2 (1.3)	1.1 (0.7)
Lat. Bend	4.1 (0.6)	6.6 (2.4)	5.6 (4.2)

* (standard deviation)

Conclusions

1. Force-displacement behavior of a cervical segment can be determined as described by using a motion transducer and a servohydraulic mechanical testing system.
2. For a flexion-distraction lesion at C5-6 fixed with interspinous wiring, stiffness in flexion-extension is four times that of the intact spine; and in axial rotation and lateral bending, the stiffness is about one-half of that of the intact. With interspinous wiring about one-half the intact flexion-extension is allowed (for +5 newtons applied force).
3. For a flexion-distraction lesion at C5-6 fixed with a segmentally wired U rod, the stiffness in all three rotations is probably no different than the intact spine. However, about one-sixth the intact flexion-extension is allowed (for +5 newtons applied force)■

Biomechanical Study of Spinal Fusion and Its Effect on the Free Segments

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Objectives—The overall objective of this project is to investigate the biomechanics of fusion in the lumbar and thoracic regions of the human spine and its mechanical effect on adjacent free motion segments.

Methods—The methodology to achieve the goals of this study include:

1. Experimental studies to obtain data describing the geometry and load bearing properties of the spinal segments;
2. Development of a mathematical model to adequately simulate the in vivo response of the human spine to physiologic loads; and
3. A parametric study, using the above mathematical model, to elucidate the effects of various fusion parameters on the biomechanics of the adjacent spinal segments.

Experimental Studies—Experimental studies using fresh human cadaver spine specimens have been carried out to obtain data describing the load-deformation properties of lumbar and thoracic spine seg-

ments under axial compressive loads and moments. In order to provide more detailed information on the posterior load path through the facet joints, a series of experiments were performed on single motion segments of the lumbar spine. The contact area, pressure distribution, and load transmitted across the facet joints were quantified using Fuji Prescale pressure-sensitive film for axial compressive loads and extension moments. Further studies are underway using specimens consisting of multiple spinal segments subjected to axial loads as well as torsional moments.

The kinematics of the spinal motion are significantly affected by the motion coupling effect of the facet joints. In order to understand this coupling phenomenon, the three-dimensional geometry of the articulating facet surfaces is being studied. The facet surfaces of each of the thoracic levels (T1 to T12) were mapped using a 3-D digitizer. Each facet surface was then approximated by a plane that is defined with respect to a local reference system via two angles. The pattern of the facet angles gives significant insight into the motion coupling behavior as a function of vertebral level (1 to 12) in the thoracic spine. A similar study is underway to investigate the 3-D orientation of lumbar facet surfaces.

A Three-Dimensional Spine Model—A finite element model of the spine has been developed that incorporates an interactive optimization procedure to identify segmental stiffness properties such that the model's displacement response matches that of the in vivo spine. These response data are taken from pre-corrective and post-corrective X-rays, and the loading imparted by the corrective instrumentation is known.

Each spinal motion segment is modeled as a finite element beam, with end nodes located at the centroids of adjacent vertebral bodies as shown by X-ray. Standard three-dimensional linear elastic beam elements are utilized. However, the model includes geometric nonlinearity due to large displacements. The segmental stiffness properties to be identified are the parameters of the finite element stiffness matrices.

Nodal error functions are calculated based on the difference between the model's displacement and the actual displacement at each node. Any of these nodal error functions can be chosen as the objective function to be minimized, while others (which have been previously minimized) are formed into constraints. Then, using a state-space gradient projection method, the stiffness parameters are altered such that the objective function is reduced without increasing any of the constraint functions. This model is being further refined to facilitate its use in conducting the parametric study mentioned earlier■

Head/Neck/Upper Torso Response to Dynamic Loading

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Sponsor: National Institute of General Medical Sciences

The investigation involves the construction and instrumentation of a replica of a human head, neck, and upper torso, including the skeletal system with rib cage, disks, ligaments, and major muscles. The model also includes the major organ systems of the thorax: heart, lung, and major blood vessel systems.

The model is to be used in vehicular impact studies in which 75 channels of data are to be collected from transducers and gauges placed on the various structural elements and features of the model, including heart, vessels, disks, and muscles. The actual mechanical properties of the various human organ systems will be approximated by using materials with appropriate mechanical properties in the construction of the various model parts.

The investigator also proposes to program a computer model of this system and validate it with data gathered from experiments with the physical model. It is anticipated that the data obtained from these studies will lead to a system for the evaluation of protective devices for the human body■

The Traumatology of the Head and Neck

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Sponsor: National Institute of General Medical Sciences

The investigator continues to extend his data of the finite element computer model of the human and subhuman primate head and neck. The skull and cervical vertebrae modeling have been completed. The main thrust of this continuing investigation will involve the modeling of the origins and insertions of

head and neck musculature, as well as the attachments of ligamentous elements and intervertebral disks. The finite element model of the subhuman primate will be validated in the laboratory.

The Morphological Changes in the Lumbar Intervertebral Foramina in Normal and Abnormal Motion Segments After Distraction

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Sponsor: University of Strathclyde

The intervertebral foramina of the lumbar spine have been incriminated as potential sources of low back pain. Using a molding technique, an anatomical study of the lumbar intervertebral foramina in human spines was performed to ascertain (i) actual foraminal shape and size with and without distraction, (ii) the effects of intervertebral disc abnormalities upon them, and (iii) the accuracy of various simple radiological measurements. The lumbar foramina were predominantly oval in outline when the disc was normal and auricular when it was abnormal. There were large variations in their minimal cross-sectional area but certain trends were established including the effect of disc degeneration upon them.

The effect of distraction on the foramen was analyzed to ascertain how this influenced any change in foraminal area. Instrument distraction of the neural arches converted the auricular foramen into a more rounded configuration and increased the foraminal area by an average of 20 percent. Small foramina and those in association with abnormal discs showed the greatest increase while those that were large only opened to a minor extent. Excision of the capsules of the facet joints, performed after posterior distraction, did not significantly increase the size of the foramen nor did subsequent anterior distraction. The clinical relevance of this anatomical study suggests that the height and area of the intervertebral foramen may be relevant in some spinal pain syndromes.

C. Human Locomotion and Gait Training

Control of Human Locomotion

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

The contribution of operant conditioning to human locomotion has been a neglected field. The proposed work will continue to study operant (discriminative stimulus) control of muscle electrical activity, EMG, and movements as people walk on a motorized treadmill.

One major aim of the work is to understand cooperation or competition between muscles of different actions or at different joints, when coordination is controlled by public events that are remote from the moving muscles. Separate or co-control that is produced over one or more muscles may reveal possibly obligatory neural or biomechanical machinery. A computer will deliver lights, judge subsequent EMG responses, and deliver a high or low tone after a success or failure, respectively.

A second major aim is to search for presumptive movement-produced stimuli—private events, such as mechanical deformations of tissue that excite proprioceptors or tactile receptors. During the coming year, work that has shown an extensive role for operant conditioning in human motor control will be summarized and extended. Wholesale shifts in rhythmic locomotor patterns will continue to be examined for their implications as to eye-limb coordination. In addition, investigations so far have amply documented the existence of movement-produced stimulation. In the next year, some experiments will attempt to specifically condition such private control.

Results as a whole will help to establish the reflexive or acquired origins of movement to aid (i) understanding of bodily mechanism of rhythm generation and, (ii) learning of movements and/or movement sense by normal or gaitdisordered individuals.

Evaluation of Methods to Measure Locomotion Performance and Activity

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Sponsor: National Institute of Handicapped Research

There are now a number of relatively inexpensive methods for measuring characteristics of gait of individual patients and for assessing the amount of activity carried out by individual patients. Some of these methods are designed primarily for clinical use; others offer new possibilities for evaluating the usefulness of experimental devices and treatment methods.

Among the systems being studied are (i) the Moss Gait Mat, (ii) the use of a 4-channel physiological ambulatory monitoring device that will record the number of steps and heartbeats against time for 24 hours, and (iii) a questionnaire developed by H.B.J. Day, of the Limb Fitting Service in England. Results from these and other methods will be correlated to determine how each or combinations of them can be used efficiently■

Quantitative Interpretation of EMG During Gait

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A major concern in the evaluation of neuromuscular gait disorders is the lack of adequate knowledge about the relationship between EMG signals and actual muscle effort. This currently limits our understanding needed for clinically interpreting dynamic EMG recordings. In most gait EMG analysis, interpretation of the signal is recorded as only whether a muscle under study is ON or OFF; in some, the interpretation of muscle effort is related in some way to the intensity of this ON signal. This classification is straightforward in normal subjects where clear differences between periods of activity and inactivity may be observed with obvious boundaries and large amplitude differences. This is not the case in many gait disorders, i.e., cerebral palsy, where muscles may be active throughout the gait cycle, (with some variation in amplitude) or where there may be several bursts per gait cycle with intervening activity which may or may not be distinguishable from low-amplitude noise and interference. We are seeking to develop a more refined method of interpreting EMG recordings by examining such recordings in a group of subjects with gait disorders and evaluating the major characteristics, in order to obtain a better clinical interpretation of EMG recordings and in order to shed more light on actual muscle effort.

Two approaches to EMG feature extraction are being evaluated for seven major muscles (groups) of the lower limb recorded from surface fine-wire electrodes (gastrocnemius, anterior tibialis, rectus femoris, gluteus maximus, gluteus medius, medial hamstrings, and adductors). The first of the approaches is modeled on the traditional binary subjective classification, and is being implemented as an automated computer determination of the ON/OFF pattern by integrating the absolute value of the full-wave rectified signal with a variety of moving-window-average filters to examine its effect on the discriminated features.

In the second approach, instead of applying a threshold decision to the resulting smoothed data, the Fourier series representation of the EMG envelope is computed with 13 coefficients retained. The statistical methodology of cluster analyses is then applied to this data, in order to determine whether classifications or groupings based on EMG binary (ON/OFF) or Fourier coefficient data can be made. We also will evaluate the effect of going from a binary classification to tertiary or quaternary, etc. (the dynamic range of the signals will be partitioned into 2, 3, 4, or more levels), and time and level data will be used in the classification algorithms. The ability to develop discrete, well-separated clusters in the patient data will be compared for each partitioning level, and the optimal number of levels of coefficient will be determined. The classifications resulting from both EMG processing schemes will be compared with each other, with the classifications from kinematic and force data, and with clinical judgements. On this basis the optimal processing methodology for gait EMG signals is to be selected■

Mechanical Energy Analysis of Abnormal Gait

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We have previously examined the validity of using mechanical measures of work to indicate the metabolic energy consumption during normal gait. These mechanical measures were: (i) mechanical work done on the center of mass per kilogram body mass per second (W cm), calculated by integration of ground reaction forces measured by force platforms; (ii) total body segmental work per kilogram body mass per second (W seg), calculated from individual body segment energies measured by motion analysis; and (iii) the sum of the normalized absolute moment impulses per second acting on the joints of the lower extremities (M), calculated from both force and motion data. The results of this previous work indicate that, for normal gait, there are strong linear relationships between mechanical work or normalized moment impulse per second and energy consumption per second. The linear relationships between these mechanical parameters measured per meter, however, were not as strong.

The work in this granting period has begun to focus on the application of all these facts to energy analyses of pathological gait. In moving toward this objective, our goal has been, first, the examination of elderly patients with degenerative arthritis. We have examined a group of subjects with degenerative arthritis of only one knee and have published these results. Efforts are continuing to examine subjects with multijoint involvement. Examination of such patients in this last year has shown that it is impossible to obtain the metabolic consumption of such patients with accuracy if treadmill walking is used. Such patients have a difficult time maintaining a steady state on a treadmill when paced by the speed of the treadmill, with or without cadence monitoring. As a consequence, to obtain metabolic energy consumption data to compare to mechanical factors of gait, we are currently exploring the use of the Beckman Breath-by-Breath analyzer in such patients walking on the treadmill and walking with free speed on a flat and level ground. This will enable us to determine the variation over time of such measurements, and allow us to obtain either an average or representative time period to compare to single-cycle mechanical energy measurements.

Work also has progressed in the area of refining our mechanical energy processing techniques for routine clinical use. The acquisition of a VICON automation motion system, and the now routine use of four force platforms within the laboratory, provide us with the opportunity of incorporating mechanical energy measurements as part of the routine clinical procedure for all gait studies we perform. This opportunity has required modifying many of our software routines to allow the calculation and graphing of the mechanical energy parameters automatically, much as our motion and EMG data are currently handled. This task is expected to be completed by the end of the present granting year.

Objective Interpretation of Gait Analysis Data

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The goal of this project is to produce a reliable objective method for the clinical interpretation of measured gait parameters obtained in laboratory testing. This includes data obtained from monitoring limb segment motions, EMG activity (muscle effort), and fast-floor ground reaction forces, and the measuring of metabolic (and the calculating of mechanical) energy consumption in association with routine clinical information, i.e., diagnosis, medical treatment, and physical examination.

In this granting period, work has proceeded well in all three aspects (development of a gait typology, data management, and clinical report generation) of this project.

In the past year our efforts have been focused on further examining and refining of the proper feature extraction technique we have utilized for examining time-varying kinematic gait parameters. This technique has involved the use of 13 Fourier coefficients to represent the data. Such coefficients by themselves do not have direct counterparts or physiological representations which can be interpreted easily by clinicians. We have implemented a software program which allows us to reproduce a given time-varying parameter from any one or a number of these coefficients, and are currently examining the possibility of utilizing this technique to determine the clinical meaning of one or a combination of such coefficients. In addition, because various aspects of such time-

varying variables as knee flexion/extension motion can be readily identified (by clinicians knowledgeable about pathological gait) as being important and representing abnormalities, the evaluation of maximums and minimums (with the percent of cycle) in these curves is also being examined. Work to date reveals that both methods may need to be used to properly represent and select features for pattern recognition techniques. However, under what conditions each one is to be utilized is a matter that cannot be predicted at this time.

Data Management—With so many items to be measured, so much data to be obtained per patient, and the need to examine a great many subjects to properly and efficiently achieve our goal of developing an expert clinically applicable gait interpretation system, a sophisticated computer-based data management system is required. This has been recognized from the outset of our proposal. A major amount of the work establishing the data management system was to be performed in this year's (1984) effort.

Various data management schemes and programs already existing have been investigated. We feel that the best approach is to utilize a commercially available system and make software modifications to it to suit the purposes of our research goals. This led to the discovery that the RS1 Data Management System, developed by BBN of Cambridge, seems ideal for our purpose. A key feature of the expert clinical interpretation system we are to develop involves the analyses of time-varying waveforms, sophisticated statistical analyses packages, graphical routines, and recently developed pattern-recognition clustering analyses methods.

We are currently implementing this system's use in our laboratory. These efforts consist of software developments to accomplish the following:

1. The setting up of a file structure for the incorporation of all pertinent clinical information needed to be evaluated in conjunction with gait data. Such information includes patient name, age, sex, physician, diagnosis, subdiagnosis, range of motion of all lower extremity joints, number and type of all ancillary devices, and treatment history by type and time (medication, physical therapy, and all types of surgical procedures);
2. Incorporation of processed gait data (as described above);
3. Graphic routines to output information. This includes both a standard output graphic package comparing differing variables, and the ability, upon request, to alter variables for comparison for particular purposes;
4. The use of statistical packages to evaluate new data and compare it to old data of the same patient (or to similar types of patients) in order to provide an on-line, real-time status report as to how the patient is performing; and
5. The inclusion of mathematical clustering analyses and classification principles to provide patient pattern recognition.

The proper implementation of all these elements is no minor effort. Such a system must incorporate new information about the same patient on subsequent testing, as well as new information from new patients. This must be done in such a way as to assure flexibility in file structuring—in order to be efficient in time and disc storage. To incorporate this feature requires the most up-to-date principles of data management software programming.

Report Generation—The system for report generation is proceeding according to the original plan. At the moment, various methods are being explored. In the first half of this year we have implemented a word processing type of report-generation scheme. This leads the clinician through the interpretation of gait data (an interactive step-by-step process) to assure that all data are examined and interpretation of each measurement is made. Its use has been tested on physical therapists and physicians who have had only the standard presentation of kinesiology as part of their P.T. or medical school courses. Utilizing only the graphic output and written data of a patient, we have tested this system and have been able to reduce the training period of such individuals from 6–9 months to 6 weeks.

However, we have found the major problem encountered with such a system is still that it fails to allow such individuals the opportunity to properly weigh the importance of each measurement, and to incorporate clinical information in the process of drawing proper conclusions about patient status or the efficacy of past and future treatments. This was not an unexpected finding. It reinforces our belief in the need to develop a pattern recognition system, thereby producing a functional performance index. It also has assisted us in determining which aspect of this pattern recognition system needs emphasis and refinement—and what the significant limitations in such a pattern recognition scheme are.

Within the next several months there is to be one major publication related to our development of a gait typology for ambulatory children with cerebral palsy■

Studies of Normal and Abnormal Motion

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

During the period from July 1, 1983, to June 30, 1984, the Kinesiology Research Laboratory continued its investigations of functional performance of normal persons and of patients with a variety of physical disabilities. The latter part of this period was saddened by the death of Dr. M. Patricia Murray.

The first of two studies published during this period dealt with the gait patterns of seven above-knee amputees who were tested using prostheses with constant-friction knee components and using hydraulic swing-control knee components. Their multiple displacement patterns, stride dimensions, and temporal components were measured during slow, free-speed, and fast walking. Gait with the hydraulic-type prostheses was improved over gait with the constant-friction type. With the hydraulic component, the amputees had a wider range of walking speeds, the durations of the stance phases on the prosthetic and sound limb showed less inequality, and forward motion was smoother. Several improvements toward normal were also seen in the displacement patterns of the prosthetic limb during walking with the hydraulic component, including the patterns of knee flexion-extension and vertical displacement of the heel and toe on the prosthetic side.

Despite gait improvements with the hydraulic component, many abnormalities were retained that were present with the constant-friction component. These included inequality in successive swing phases, excessive lateral lurching toward the prosthetic side during prosthetic single-limb support, and vaulting during sound single-limb support. Some of these abnormalities may be habit patterns and others may be necessary compensatory maneuvers for an above-knee amputee.

A second study continued our series of investigations of patients with total hip joint replacements. The purpose of this study was to do objective kinesiologic testing of a group of patients before and after revision of total hip replacements due to noninfectious loosening. Baseline data to identify which components of function decline with loosening (and to what degree), and to identify which components of function improve after revision, were provided by a control group with uncomplicated primary total hip arthroplasties.

There were 31 primary total hip replacements and 31 total hip revisions. Measurements of functional performance were made before surgery and 6 months afterward. Data collected included: range of motion of the hip, strength of hip abductor and adductor muscles during maximum isometric contractions, weight distribution between the feet during standing, forces applied to canes or crutches during walking, and multiple simultaneous displacement patterns during free-speed and fast walking. Each patient also answered a questionnaire about pain and performance of daily activities.

As a result of primary total hip replacement, patients in the control group regained a significant amount of function (in the absence of postoperative complications), but they did not reach normal levels of function. As a result of loosening of the prosthetic components, functional abilities of the patient declined to levels approximately the same as before the primary surgery, with a few exceptions. Loss of motion into hip flexion and extension, decrease of hip adductor muscle strength, and decrease in the use of hip flexion-extension during walking were not as severe in those with loosening as in those with coxarthrosis prior to initial total hip replacement.

After replacement of the loose prosthetic components, function in the patient returned to levels approximating those found after primary total hip replacement. Patients with revision, however, tended to have a greater reliance on assistive devices after surgery than those in the control group. A 2-year follow-up of these same patients is in progress.

In addition, work is nearly completed on two studies of normal function. The first is a study of the kinematics and electromyography of slow, free, and fast walking and the second is a study of strength of the knee flexor and extensor muscles of women 20 to 85 years of age■

A Self-Contained Portable Force and Movement Measurement System to Aid Diagnosis and Rehabilitation of Human Movement Disorders

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Sponsor: National Institute of Handicapped Research

The work described here is a continuation of an effort which started with the specific aim of improving above-knee amputee gait training through development of instrumentation for measurement of gait parameters and biofeedback of gait parameters. As prototype hardware was completed, its general applicability became apparent. Although the immediate focus of the effort remains on above-knee gait training, the criteria that guide design decisions are more global. A self-contained, portable, force and movement meaurement system has many applications in diagnosis and rehabilitation.

The gait training aid (Strider) is a microcomputer-based instrument that has been programmed to provide the following:

1. Threshold and/or proportional audio biofeedback of the prosthesis weightbearing (is the proper weight being applied to the prosthesis?).
2. Average peak weightbearing during a series of steps.
3. Percentage of stance cycles when the adjustable weightbearing threshold was attained.
4. Threshold and/or proportional audio biofeedback of hip extension angle (is the person standing erect during stance?).
5. Percentages of cycles when the hip extension threshold was exceeded during stance.

During the past year, several subtle changes have been made in the instrument's software, but the main effort has been directed toward improved force and movement transducers.

For a weightbearing transducer to be clinically acceptable, it must be compatible with existing postoperative prostheses and training procedures. Such a transducer has been designed and built. It uses a thin cylinder of elastomer to isolate the axial load on the prosthesis from the large bending moments which occur in the shank. This allows a strain gauge to measure one type of loading without being substantially affected by large stresses in other directions.

New Movement Transducer

The movement transducer also has changed dramatically. The new system is essentially a radio direction finder. A small transmitting antenna is placed on one body segment and a crossed pair of receiving antennae are placed on another body segment. Appropriate processing of the signals from the two receiving antennae yields a very well-behaved indication of the angle between the transmitter and receiver. A clinically rugged version of the transmitter/receiver system has been built.

The Strider has been used and evaluated by the physical therapy staff at the Massachusetts General Hospital. The therapists' reaction was enthusiastic. The system looked good and performed consistently and reliably, doing what it was designed to do. It seems to enhance learning at some points in the amputee's training.

As a result of clinical testing, improvements to the system are being considered. Most of them involve increasing the flexibility and the ease of use of device. Particular concerns are allowing the therapist more flexibility in changing the threshold values, providing more alternative forms of biofeedback, eliminating wires, and reducing the weight of the portions of the system worn by the patient■

Locomotion: Idling Metabolism and Gait Dynamics

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Sponsor: National Institutes of Health
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The long-term goals reflected in this proposal are:

1. To determine the manner in which muscles and populations of fibers within muscles are recruited during locomotion; and
2. To investigate the relationship between muscular activity and muscular-metabolism.

In previous work, we have described the spatial recruitment patterns that occur within and among mammalian muscles during exercise. Also, we recently have found that the magnitude and distribution patterns of blood flow within and among muscles of rats vary with the fiber type composition of the muscles and with locomotory speed, and that muscle blood flow increases with time during exercise to fatigue at a constant speed. We have concluded from this work that muscle blood flow patterns are closely related to muscle fiber-recruitment patterns.

Two immediate questions emanate from our previous work:

1. Are the absolute magnitudes and the patterns of blood flow observed within and among the rat muscles representative of other mammals, or are they unique to laboratory rodents?
2. Are progressive changes in muscle fiber recruitment responsible for the gradual elevations in muscle blood flow that occur over time during exercise, or are other mechanisms involved?

To answer the first of these questions, blood flow within and among the muscles of pigs and dogs will be determined during exercise. To answer the second, we will test three hypotheses that may explain the progressive increases in muscle blood flow that occur with time during exercise: (i) the elevations result from progressive recruitment of additional motor units in the muscles as fibers fatigue, (ii) the elevations result from a progressive rise in body temperature, or (iii) the elevations result from progressive accumulation of vasodilator substance in the muscles. Answers to these questions will significantly further our understanding of the patterns of muscle fiber activity that occur during exercise and the accompanying metabolic support of the muscular activity■

Medical Gastrocnemius Muscle Function in Locomotion

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

The specific hypothesis that central nervous system control of locomotion is focused on distinct parts of individual muscles rather than on whole muscles or synergistic groups will be tested. The activity of single motor units in distinct parts of the triceps surae muscle group of cats during a broad range of stepping behaviors will be recorded. Each motor unit recorded will be carefully characterized using physiological criteria, and its location in the muscle examined by glycogen depletion and histochemical analysis. The pattern of recruitment of motor units in each part of each of the muscles will be correlated with the physiological properties of those units. These patterns will then be compared in different parts of the muscle to determine if motor units are recruited with any level of independence in different parts of the same muscle.

The results of this study are expected to be significant in establishing guidelines for studies of the mechanisms and the specificity of motor control during behavior. They also should be of use to clinicians, especially in neurology and rehabilitation medicine, in the diagnosis, treatment, and evaluation of patients with disorders of movement, especially those involving the locomotor apparatus■

Development of a Clinically Applicable Model of a Gait

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Analysis of the influence of the states and controls can be an important tool in the evaluation of pathological gait. It is well known, clinically, that alterations in one part of the leg, i.e., a tendon transfer or muscle release around the ankle, produce changes in the kinematics of all limb segments. The analysis of the influence of the states and controls provides a means for explaining the propagation of a localized change throughout the system. More importantly, it may be useful in aiding the identification of those areas where clinical interventions would be most beneficial. For example, if the shank acceleration is too low, so that the knee cannot come to full extension at heel strike, we would determine which variables had positive and negative influences on shank acceleration. Consideration would be given to those clinical treatments that had a net positive effect on the shank acceleration.

In the coming year we are planning to:

1. Apply the three-dimensional model to evaluate the primary changes in a pathological gait following a surgical procedure;
2. Quantitatively evaluate the effects of mass and mass distribution in prostheses for above-knee amputees with the intent of developing design criteria;
3. Complete the measurement of the results of the effect of the passive elastic moment at the knee and evaluate the effect of hip and knee passive moment during gait■

Feature Extraction for EMG Gait Analysis

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Introduction—Objective gait assessment is recognized as a necessary component in evaluating locomotor disabilities. Computerized evaluation of electromyographic (EMG) data is one component of this assessment. Essential to computerized EMG evaluation is the extraction of important waveform features that are easily understood and amenable to further analysis. Since the linear envelope is the accepted modality for describing the EMG waveform in gait, a good feature extractor would indicate the times and intensities of phases of EMG activity.

Methodology—A method that will extract the times and intensities of EMG activity phases is the Tauberian approximation shown in equation (1) below

$$y(t) = \sum_{i=1}^{M} a_i x(t-\tau_i) \qquad (1)$$

where y(t) is the approximation of the EMG envelope over one stride; x(t) is a basis function; τ_i is the time when some activity occurs; a_i is the intensity of that phase of activity; and M is equal to the number of phases. The features are a_i and t_i. When considering the linear envelope on the normalized time scale, that is, time between 0 and 100 percent of a stride, a very suitable basis function is the Gaussian function

$$x(t) = \exp[-t^2/2\sigma^2] \; |t| \leq 2/4\sigma \qquad (2)$$

with σ having a range between .04 and .08. Features are calculated through equation 3

$$H(w) = \frac{Y(w)}{X(w)} = \sum_{i=1} a_i \exp[-j\tau_i w] \qquad (3)$$

This equation is solved by using the discrete Fourier transforms of the average EMG envelope, Y(w), and basis function, X(w), to produce H(w), and then using the Prony method to calculate the a_i and τ_i. (Note that the scale factor for x(t) is incorporated into a_i, giving x(t) a peak value of 1.0).

Results—In an approximation of tibialis anterior muscle EMG of a normal female walking at 0.97 meters per second with a stride time of 1.1 second, the time scale is percent of stride and the waveform has been normalized to have an average of 1.0. Five terms were used and the features are listed in Table I. The technique extracts the phase of activity during early stance, the longer duration phase during the stance-to-swing transition, and the phase of activity during late swing. Notice that small intensity activity is used to complete the monophasic burst during early stance.

TABLE 1.

EMG Envelope Features

Time	Amplitude
6.1	2.34
16.1	0.44
70.9	2.47
80.1	2.59
94.7	1.52

This approximation was attempted on five different leg muscles in five normal individuals walking at various speeds. There was good correspondence in II approximations. Two parameters are vitally important when using this technique. These are the number of terms, M, and the duration of the basis function, σ. These parameters are easily adjusted with automation to produce a good approximation■

D. Upper Limb Function

Processes Underlying Arm Trajectory Formation

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Sponsor: National Institutes of Health
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A series of experiments has been outlined that involve kinematic observations made under a variety of conditions in animals, normal subjects, and patients affected by a sensory neuropathy. In parallel with these kinematic observations, we are proposing a computer simulation research directed at defining one possible control strategy subserving the formation of arm trajectories. The idea underlying the simulation work is the potential valley concept, which derives from spring-like muscle properties.

The following experiments are proposed:

1. Alteration of Biomechanical Structure. We plan to study the kinematic role of those muscles that span two joints. In conjunction with this study, we also will analyze the electrical activity of the two-joint muscles and compare it with the one-joint muscles.

2. Studies of Patients with Sensory Losses. Kinematic studies will be performed in patients affected by a neuropathy of unknown origin that totally or partially deprives these subjects of joint position sense, cutaneous sensations, and proprioceptive feedback from muscles.

3. Deafferentation of Monkeys. Depending upon the outcome of the patients' study, the question of the role of proprioceptive feedback during trajectory formation will be studied in monkeys.

4. Velocity-Profile Invariance under Gravity Loading. In these studies, we will utilize normal subjects and perform three-dimensional recordings with the Selspot.

5. Alteration of Segmental Parameters. Again with the Selspot, we will see how kinematic patterns of the arm are changed when masses are attached to the arm and rods are attached to the hand.

6. Arm Movements under Orientation Constraints. We propose to contrast movements executed under hand orientation constraints with those performed without such constraints to learn whether the extra kinematic complexity is manifested through different types of trajectories.

7. Simulation of Movement. We will focus on evaluating the implementation of the potential energy valley idea, particularly the way in which this hypothesis might allow the formation of trajectories with realistic kinematic features.

It should be stressed that both the biological studies and the simulation of work derive, at least in part, from the assumption that muscle spring-like properties and factors intrinsic to the biomechanical structure of the arm may be used by the controller to form arm trajectories. The simulation model will be tested by applying some of the same broad class of disturbances in the simulation as were applied in the biological experiments above.

E. Other

Bone In Vivo and In Vitro Stress and Strain Patterns

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Bone can adapt to mechanical stress. In recent years there has been a renewed interest in the mechanisms by which bone responds to disuse and to overuse. Disuse changes associated with immobilization, paralysis, and weightlessness and overuse changes associated with repetitive loading during activity have received particular attention. Many studies have been published on the mechanical properties of cortical bone, but few have examined the variation of properties in the growing animal. The purpose of this study is to characterize bone growth (changes in geometric, biochemical, and biomechanical properties) in the maturing animal. The effects of hypokinesia, hyperkinesia, and diet-induced bone disease are being examined.

In previous studies the geometric, structural, and material properties of growing rats were reported. Bone cross-sectional geometry was determined using a computerized numerical procedure. In vitro structural and material properties were determined from both elastic non-failure, and failure bending and torsion tests; in vivo strains were recorded during gait using a technique developed in our laboratories. During growth, the geometric, structural, and material properties increased rapidly until maturity. These increases were best represented by a power curve fit of the data. Comparison of the properties of stressed and non-stressed (voluntary) exercised animals with

the results revealed that intensive exercise produced significant ($P<0.01$) bone hypotrophy (e.g., decreased cross-sectional growth rate, decrease in bone length) as well as significant reduction in structural and material properties. These results question the prevailing belief that exercise is always beneficial. In addition, the data suggest that immature bone maintains or increases material integrity in response to an optimum stress range. Stresses above or below this range have a negative effect on bone material.

Currently, we are investigating the response of bone during disuse. A hind limb suspended and unloaded hypokinetic rat model is being used to examine the biochemical and biomechanial properties of maturing rats. This study will provide information valuable to basic biology, space biology, and the clinician by giving insight into the role of gravity and mechanical stress on the control and functional adaptation of bone characteristics. These data will aid in the development of proper treatment strategies to prevent or minimize bone changes associated with disuse.

Future studies will be directed toward examination of the effects of diet-induced bone diseases (osteoporosis, osteomalacia, and osteolathyrism) on bone properties. In addition, in vitro torsion, bending, and fatigue studies will be performed on immature primate cortical bone. Subsequent comparison of growing rat and primate cortical bone biochemical and biomechanical properties will provide additional insight into modeling (cell activation → osteoblastic formation) and remodeling (cell activation → osteoblastic resortion → osteoblastic formation) processes, respectively. Formulation of a theoretical growth model for modeling and remodeling bone may then be possible. Such a model may allow us to predict the behavior of bone in long-term hypokinetic (disuse, microgravity) and hyperkinetic conditions. Extrapolations of these data to humans under similar conditions also may be possible■

Human Response and Lower Extremity Injury

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

The mechanics of human injury is a complex process. External forces are transmitted to the human musculoskeletal system; the system responds in the manner of displacements and rotations. Stresses are induced in the tissues and under some conditions the tissues are disrupted. When the forces are not constant, prediction of the likelihood of injury and the severity of the forces is difficult.

This proposal presents a research program investigating the mechanics of lower extremity injury, specifically injuries to the knee, tibia, and ankle that typically occur in snow skiing. Snow skiing is studied because (i) the lower extremity injury rate is high, (ii) the forces transmitted to the foot can be measured, (iii) response of the lower extremity can be measured, and (iv) safety devices can reduce the high rate of injuries. Specialized laboratory and field test equipment have been developed to measure and analyze the forces between the boot and the ski; the rotations occurring at the ankle, knee, and pelvis; and the integrated EMG from muscle groups during skiing and especially during falling, when severe loading occurs and the likelihood of injury increases. The field measurements identify the injury environment, and the laboratory experiments clarify how the lower extremity responds to dynamic loading. This is the identification problem for the lower extremity.

The true severity of the typical skiing environment and the contributions of the musculature to influence the likelihood of injury will be clarified. The common misconception that the forces of skiing are compared to typical tibia fracture strength and knee ligament strength will be corrected. The erroneous concept is widespread, extending to standards organizations, the industry, and the public alike. The error has major impact on the design of safety devices, on the evaluation and acceptance of safety devices, and on the training and instruction given the public. Efforts are directed to development of meaningful standards of safety■

Foot Interface Pressure Study

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Peripheral neuropathy associated with diseases such as diabetes mellitus often causes severe deficiency in transmission of sensory modalities in the lower extremities. Such losses impair the protective mechanisms and render the extremities vulnerable to the effects of applied forces of daily ambulatory

activity. This not only results in skin ulcerations, but also may cause hyperemia and inflammation secondary to trauma. Many diabetic patients with foot ulcers are seen at the VA Medical Center, and often there is difficulty in achieving healing because means to reduce repetitive plantar pressure are inadequate. Required are criteria for prescribing interface materials and means for evaluating effectiveness of materials chosen.

Hypotheses

The hypotheses in this study are the following:

1. Plantar pressure ulcers in hypo or insensitive feet may be effectively treated by use of appropriate interface materials.
2. Physical properties appropriate for the selection of interface materials can be determined.
3. Adequacy of static load distribution properties of an interface material can be determined by use of a barograph.

Methodology

Clinical Testing—Both diabetic and non-diabetic patients at the VAMC with established findings of peripheral neuropathy are seen periodically to monitor condition of the insole and, for those with ulcerations of the plantar surface, to measure and record the width, breadth, and depth of the ulcer. Patients' weight and ambulatory habits are noted, and the thickness of the used insoles are measured at points of maximum compression set. If the thickness is 50 percent or less of the original thickness, the insole is collected and a new one issued. Thickness of the collected insole is monitored for a week to note any recovery. As a result of static load testing in the laboratory, four pairs of insoles are issued to permit daily changes allowing a 4-day interval for partial recovery in thickness and restoration of cushioning properties. During the initial phase, medium density Plastazote was used with over 50 patients. Recently, Aliplast 4E was introduced to obtain comparative performance results.

Laboratory Testing—Both time-related and non-time-related properties of a variety of commercially available, so-called closed-cell, cellular plastic materials have been preliminarily evaluated. Time-related testing consists of statically loading samples to note changes in thickness as a function of time. After a few days the thickness stabilizes, then the load is removed and the rate of recovery is noted. The slow compression takes place because the closed cells are not impermeable, but allow gases to escape from the cells. Potential energy, stored in the deformed plastic matrix, causes air to be drawn back into the cells when the material is unloaded. Static testing has been done with loads representing 10, 20, and 30 psi.

Non-time-related properties have been evaluated using a manually operated, mechanical X-Y recorder. Samples are loaded and unloaded at rates resembling those during walking. The relation of thickness to pressure is approximated by the following general form:

$$t = t_0 [(1-t) e^{-ap} + r]$$

where t = thickness
t_0 = unloaded thickness
r = compressibility factor
a = compliance factor
p = applied load

The compressibility factor is a ratio tp/t_0, where tp is the plateau thickness at high pressure, usually in excess of 70 psi. Both the compressibility and compliance factors are independent properties of different materials. The shape of the curve depicting the thickness-pressure relation resembles the gas law relation $PV^n = C$ because a part of the work done on the cellular material during compression is stored as potential energy in the gases contained within the cells.

Plans for the Future—Continue the collection of data from the clinical application of different interface materials and different configurations of insoles for relative effectiveness in protecting the plantar area, for durability, and for factors unifying the weight of a patient, contour of the foot, ambulatory activity level, and footwear design. Continue seeking footwear design appropriate for this category of patient. Continue to explore means to locally reduce normal and shear forces in areas of plantar ulcers and to evaluate the efficacy of such means■

[See also **III. Total Joint Replacement and other Orthopaedic Implants, A. General**, Biomechanics of Bone Resorption/Regeneration of the Bone-Implant Interface; and, **V. Functional Assessment**, Quantification of Motor Performance: Muscle Strength and Endurance Testing]

VII. Wound and Fracture Healing

Morphological and Clinical Studies of Microwounds in Ischemic Human Tissues

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Peripheral vascular disease (PVD) is a major cause of morbidity and mortality in this country. Approximately 30,000 lower extremity amputations are performed annually in the United States, primarily for PVD. Failure of wound healing is one of the principal problems encountered in these patients, either nonhealing of leg ulcers or nonhealing of attempted surgical intervention, such as grafting, debridement, or amputation. To date no systematic studies of wound healing have been done in patients with PVD because of the invasive nature of the methods for the study of wound healing and the tenuous nature of the affected extremities.

The method used in this study involves the creation of standardized microwounds on the extremities of individuals awaiting amputation necessitated by PVD. The wounds were made under sterile conditions using a Simlate-II bleeding-time device at sites distal to the planned amputation at predetermined times prior to amputation. The microwounds were excised from the amputation specimens immediately after amputation, placed in Karnovsky's fixative, and embedded in Epon 812 for thin sectioning for light and electron microscopy. Morphological events of dermal and epidermal wound healing were expressed as a ratio of the morphologically apparent wound age divided by the actual wound age and were related to transcutaneous oxygen tension (Tc pO_2), amputation outcome, and clinical factors such as diabetic status.

Microwounds have been studied in 15 subjects with wounds created 7 days prior to amputation. In three of those subjects additional time points were studied at approximately 2, 12, 24, 48, and 72 hours as well as 10, 14, 21, and 28 days prior to amputation. There was no morbidity from the procedure. In general, the events of healing were considerably retarded relative to normal. The dermal events of healing were significantly more retarded than the epidermal events. While the method appears to be a safe and effective means of obtaining relatively standardized wound tissue for study of the healing process in ischemic human tissue, it did not appear to be consistently useful as a predictor of amputation outcome at the selected level.

Future studies include expanding the number of subjects so that more meaningful analysis of clinical factors such as Tc pO_2, diabetic status, and amputation level may be made. Electron microscopy of selected material will be done and immunohistochemical studies of human wounds are planned.

Effect of Stress and Motion on Repair of Hard and Soft Tissues

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This research program is designed to pursue Wolff's Law on tissue healing and remodeling. Although initial immobilization after musculoskeletal trauma is necessary for tissue healing to take place, the deleterious effects of prolonged and/or over-immobilization on the repair process and of the disuse atrophy of the surrounding tissues are also well known. We have chosen two projects as areas of concentration: (i) to study the deleterious effects of large internal fixation plate systems used to immobilize long bone fractures, and (ii) to evaluate the effects of motion and stress on the repair of the medial-collateral ligaments.

In the internal fixation plate study it should be noted that by and large the currently used devices are effective in treatment of long bone fractures. However, direct osteonal bone union healing under rigid fixation must be viewed, conceptually, as a slow and unnatural way to mend fractures. In addition, the large fixation systems shield the underlying healed bone from physiological stresses and can cause atrophy or osteoporosis. At plate removal, refractures of bones are of significant clinical concern. In order to gain a better understanding and to improve the present internal fixation plate systems, we have developed new design criteria, i.e., moderate bending and torsional plate rigidities for adequate early immobilization in order to achieve callus fracture union,

and a low plate axial rigidity to minimize the stress (or strain) shielding of the underlying bone during the post-union remodeling process. A tubular cross-sectional plate, i.e., a flattened stainless steel tube filled with polyethylene, has been made. This plate has been applied to immobilized canine mid-shaft femoral osteotomy models and has been tested against the control plate (rigid plate made out of stainless steel). At 6 and 9 months postosteotomy, there were significant advantages both in terms of mechanical and structural properties of the healed bone underneath the low axial rigidity tubular plate. Morphometric evaluations of bones are in progress.

The next phase of this study will include the longer term (12 and 15 months) experimental animals as well as additional animal groups to study the effects of plate removal (recovery of bone). It is hoped our data will enable the clinician to choose a less rigid plate, e.g., tubular plate, and to select appropriate timing of plate removal on a rational basis.

In the ligament repair study, dogs and rabbits have been used as experimental animals, and a variety of treatment conditions, ranging from rigid immobilization and cage activity to immobilization plus cage activity, have been imposed to determine which set of conditions will enhance the speed and strength of ligament repair. In addition, ligament healing versus surgical repair studies have also been conducted.

The quality of the healing and repaired ligaments are being evaluated by morphological, biomechanical, and biochemical techniques. The advanced biomechanical testing procedures developed in our laboratory permit the studies of the properties of the repair line separately from, and in addition to, the bone-ligament composites. This is of great importance because the responses to the treatment regimens from various elements of the ligament composite, viz., area of repair, area of ligament proximal and distal to repair, and ligament insertion sites are different. In addition, we are measuring the joint laxity quantitatively using our newly developed apparatus. Cyclic and viscoelastic characteristics of ligaments are also being evaluated.

Currently, the healing MCLs of rabbits up to 40 weeks have been studied, but those for the dogs are limited to 6 weeks. Preliminary data indicate that early but limited motion is advantageous, and that the healed ligament is not comparable as the normal (even up to 40 weeks postoperative) in terms of strength, stiffness, and joint laxity. Additional sacrifice periods for dog MCLs up to 26 weeks are in progress. Biochemical measurements of water content, GAG, cell cellularity and collagen typing, and collagen cross-links of repairs and normal sites of the MCLs from sacrificed animals are also in progress. It is hoped that as a result of this data, additional treatment programs including exercise training can be incorporated so that determination of treatment programs on the healing ligaments will be possible.

Transcutaneous Oxygen Tension as Predictor of Wound Healing

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Transcutaneous oxygen tension has been studied for its usefulness in predicting wound healing potential in disvascular limbs. This noninvasive measure of local cutaneous perfusion has been correlated with the severity of peripheral vascular disease as determined by clinical symptoms. The relationship between local cutaneous perfusion, clinical symptoms, and sensory nerve function is currently under investigation.

Segmental transcutaneous PO_2 measurements were made on the limbs of diabetic and nondiabetic patients admitted to the Amputation and Vascular Services at the Seattle Veterans Administration Medical Center. These patients had varying degrees of peripheral vascular disease. Nondiabetic limbs with transcutaneous PO_2 values on the foot or below-the-knee of less than 20 mm Hg were significantly more likely to have rest pain or ulcers, to need an amputation, and to have failure of amputation healing than were those limbs with transcutaneous PO_2 values above 40 mm Hg. Diabetic patients show similar results, although many had ulcers coincident with transcutaneous PO_2 values greater than 40 mm Hg, suggesting factors other than inadequate cutaneous oxygen delivery may result in ulceration of diabetic limbs.

Healing of below-the-knee amputations was correlated with transcutaneous PO_2 values at that level, and amputation healing showed a strong correlation with below-the-knee transcutaneous PO_2. All patients with below-the-knee transcutaneous PO_2 values above 40 mm Hg healed, 94 percent of those with values between 20 and 40 mm Hg healed, and the healing rate where the transcutaneous PO_2 value was

less than 20 mm Hg was 47 percent.

Transcutaneous oxygen tension and laser-doppler velocimetry were compared over heated and unheated skin in which perfusion pressure was reduced by limb elevation. Results indicate that laser-doppler and transcutaneous PO_2 measurements do reflect changes in local perfusion pressure when made over warmed skin, but not when made over unwarmed skin.

The multiprobe transcutaneous oxygen tension monitor has allowed simultaneous measurements at eight sites and has enabled spatial mapping of cutaneous perfusion in disvascular limbs before and after amputation. These studies continue to elucidate the value of transcutaneous PO_2 measurement in the clinical assessment of the local circulatory status of skin■

Studies of Factors Affecting Orthopaedic Infections

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Sponsor: National Institutes of Health
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The research being undertaken is designed to investigate problems of infections in orthopaedic patients. One aspect of the study is to better understand factors leading to wound contamination in open fractures and any infections that might follow such contamination. Various factors, including the use of internal fixation devices, methods of irrigation, and time between injury and treatment, as well as underlying diseases, are being compared with infection rates and with level of tissue contamination. An animal model involving open fractures of the hamster femur using an osteotomy saw has been developed to better understand the role of internal fixation in infection. Studies have been done with Staphylococcus aureus and will be done with Proteus and an Anaerobic Streptococcus.

Studies also are being undertaken in the hamster to investigate host reponses, such as sensitivity reactions, to the implant on infection rates. Finally, rapid diagnostic techniques are being investigated for diagnosis of osteomyelitis and septic arthritis using blood, joint fluid, and aspirates. These studies should provide information on the management of patients likely to develop infections■

Stimulation of Repair of Cortical Bone Transplants by Implantation of Piezoelectric Materials

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Introduction—Microampere DC currents have been used extensively to stimulate bone formation. Traditionally, these currents are delivered to implanted electrodes by external power sources or implanted batteries. The purpose of this project is to develop a novel approach to electrical stimulation of bone healing and regeneration (including incorporation of bone transplants) by employing direct delivery of faradic, microampere currents generated during physiologic loading by a piezoelectric material incorporated in a less rigid internal fixation device. From a theoretical standpoint, assuming simple tension or compression on a piezoelectric material, the charge generated is $Q = Ad_{31}S_1$, where A is the material area, d_{31} is the piezoelectric constant, and S_1 is the stress. The current produced by application and release of load is bipolar, and the magnitude varies with frequency of loading. For 1 Hz loading, with the current output rectified by a full-wave bridge, the average current would be $2Ad_{31}S_1$. For PZT-5 ($d_{31} = 270$ pC/N), if $A = 1$ cm^2 and $S_1 = 6 \times 10 \times_6 N/m_2$ ($\cong 100$ microstrain), the average current generated would be 0.33 μA.

Methods—As a pilot study in vivo, miniature (36×6 mm) replicas of three-hole internal fixation plates were constructed of delrin bonded to a non-electroded PZT-5 ceramic bimorph or a strip of polyvinylidene fluoride (PVDF). Four plates were implanted in each of eight dogs, one active plate fixing a 1.5-cm bone graft in the ulna, another overlaying two 4-mm drill holes in the radius, and two depoled (electrically inactive) plates on the contralateral bones as controls. The entire free surface of the piezoelectric material was in direct contact with bone; plastic screws were used for fixation. Results were assessed histologically after 8 weeks. In a later in vitro experiment, four-hole Keviar/epoxy composite plates were constructed with a strain-gauged ceramic bimorph incorporated on top. For testing, the plate was attached to a canine femur with four insulated steel screws and the bone loaded in cantilever bending. Similar experiments were conducted with a bimorph bonded to a titanium plate. To generate current, repetitive loads producing 100 mi-

crostrain in the bimorph were applied at 1 and 2 Hz (load duration = 0.5 s; rise time, 0.2 s; plateau, 0.1 s; decay, 0.2 s). Bimorph output (surfaces versus vane) was connected to a full-wave diode rectifier. Average current was determined from voltage drop across a 1 M Ω resistor and a 0.47 μF capacitor shunting the rectifier output.

Results—The in vitro experiments showed that with rectification, continuous DC currents of 0.25 to 0.4 μA could be generated during a series of deformations. Without rectification, polarity varied with sign of the strain and bipolar currents were generated. The earlier in vivo study failed to show significant tissue reactions or differences on bone healing/remodeling beneath the free surface of active versus depoled bimorphs or PVDF.

Discussion and Future Plans—Our limited in vivo study suggested that the charged surface of a piezoelectric material, in itself, has no dramatic effect on osteogenesis, at least in a configuration in which charge density is low and fluctuations with stress are nearly symmetrical. Further work of this type is planned to confirm these negative results. Also, the effect of contact with piezoelectric materials on streaming potentials in underlying bone will be studied.

In the alternate mode, however, the in vitro tests demonstrated the feasibility of designing piezoelectric internal fixation plates that, during normal physical activity, could generate DC currents exceeding the 0.075 μa level identified recently as the minimum for faradic stimulation of osteogenesis. These experiments generated approximately 0.3 μa and an increase by a factor of 10 to 20 could be expected in clinical applications utilizing a proportionally larger area of piezoelectric material subjected to larger strains. This design concept offers considerable potential for research and development with respect to components, configurations, and applications for internal fixation. Materials ranging from titanium to fiber/plastic composites could be selected to enhance mechanical and stress coupling properties, while piezoelectric materials ranging from tissue compatible ceramics to polymers (PVDF) could be fabricated and poled to attain optimal current output and polarity in specific anatomical locations. Conceivably, electrical charge also could be generated by external ultrasonic energy during non-active periods.

In the next stage of this study, instrumented prototype piezoelectric plates will be implanted in dogs and current measurements made during walking. In the final stage, using rabbit and canine models, studies of effect of these piezoelectrically generated currents on bone formation will be made using implanted electrodes connected directly to the rectified plate output■

Effects of Immobilization and Motion in the Injured Tendon

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For the coming support year, the objectives are: (i) to establish the pattern of tryptic peptides of collagen from tendons of exercised chickens and compare these to the established patterns for immobilized and control birds; (ii) to continue isolation of three major cross-link peptides that elute at the same position for collagens from normal, immobilized, and exercised birds, and to perform amino acid and sequence analysis to assign a location for these peptides within the collagen molecule; (iii) to continue isolation of tendon cells from sheath, synovium, and tendon fibroblasts.

The latter cells from immobilized and exercised birds will be subjected to tension and compression in vitro. The ^{35}S-methionine labeling patterns will be compared to that of the normal birds. Particular attention will be given to the amounts of collagen, actin, and tubulin produced by the cells. The cell culture studies have taken an unusual turn. Populations of cells have been isolated: cells from sheath, synovium, and tendon proper are different in morphology, protein profile, rate of division, and adherence to substrate. On the other hand, tendon fibroblasts from a physically small tendon (flexor profundus) versus a large tendon (flexor to the gastrocnemius) appear to have minor differences in protein synthesis patterns. Consideration of physical stress on tendons led to the creation of a new culture plate that can accommodate up to 200 percent stretch. The latter has been in testing for 10 weeks as of this writing. Tendon cells in culture seem to respond to 0.1 percent compression in vitro by decreasing tubulin and increasing actin concentrations. Experiments with tension are in progress.

With respect to peptide sequencing, it is anticipated having at least three major peptides that contain either reducible or 3-hydroxypyridinium (HP) cross-links quantitated and compared among the groups in the next 6 months. The absorbence and HP patterns have been completed. Currently being used is a

170-minute, 0.1M PO_4 2.85 pH, acetonitrole gradient to elute collagen tryptic peptides. As little as 10 ug of collagen need to be injected to establish absorbence and fluorescence patterns (HP), but more material is required for radioactivity detection. It is anticipated that the amounts and location of HP cross-link sites in tendon collagen from exercised birds will be different from those of the immobilized and control counterparts. The latter patterns are different; peptide purification and analysis are underway.

Flexor Tendon Healing: Restoration of the Gliding Surface

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

Preliminary results from our laboratory suggested that primary tendon healing could be stimulated by protective passive motion which prevented tendon sheath adhesion ingrowth. This effect resulted from a cellular proliferation of the epitenon layer. An improved mechanism of repair was anticipated as a result of carefully applied and protected early motion techniques. The objectives of the first year of this grant period were to establish a model and obtain data on the intrinsic capacity for flexor tendons to heal in the absence of tendon sheath adhesion ingrowth.

An initial study was carried out in conjunction with Dr. Paul Manske at Washington University in St. Louis in which flexor-tendon segments from New Zealand white rabbits were lacerated, immobilized, and placed in tissue culture media. The tendon segments were studied by light and electron microscopy at 3-, 6-, 9-, and 12-week intervals. A characteristic sequence of repair was noted, including epitenon thickening, cellular differentiation, cell migration, and phagocytosis in each of the lacerated tendons. This response was similar to previously observed in vivo tendon healing and indicated that tendons have the inherent capacity to heal in the absence of adhesion growth. An additional study of the healing characteristics of four different species was explored in a tissue culture system. Tendon segments were studied by light and electron microscopy at 3, 6, 9, and 12 weeks. A similar pattern of repair was seen in each model, but the rate of healing differed significantly.

Other research efforts in this period have included the construction of a continuous passive motion device so that the effects of continuous motion could be compared with previous results using intermittent passive motion and immobilization techniques. The device has been constructed, and animal experimentation is ready to begin. Finally, we have established an in vivo tendon healing model in which tritiated thymidine is used to tag cells participating in the tendon healing process.

A Study of Intertrochanteric Fracture Fixation Methods

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Sponsor: University of Strathclyde

This summary reports the findings of a three-part pilot project to determine the optimum technique for the fixation of unstable intertrochanteric fractures of the femur in elderly patients with osteoporosis.

A total of 121 patients with unstable intertrochanteric fractures were studied. Eighty-two patients were treated with Kuntscher-Y nails (KY) and 39 were treated with a Honey Capener (HC) fixed-angle nail plate. Most complications were seen with the use of the HC nail plate. These were nail breakage (five), bending with loss of reduction (ten), and detachment of the plate (four). Most cases of failure could be related to a significant degree of osteoporosis which was estimated using Singh's classification.

A similar study using Richards sliding screws was conducted on 86 patients with unstable intertrochanteric fractures. There was a 4.7 percent incidence of complications which was associated with a moderate degree of osteoporosis.

Clinical experience suggests the mechanical superiority of the Richards screws and KY nails but also highlights osteoporosis as a limiting factor in the use of these internal fixation devices.

Mechanical tests were therefore performed on these two implants using an Instron testing machine. In order to investigate the effect of osteoporosis, parallel tests were conducted with the use of adjuvant bone cement.

Paired femoral specimens with a standardized fracture were tested with and without the addition of cement. The degrees of osteoporosis were assessed for the specimens using Singh's classification. The total strength of the Richards screw fixation ranged

from 280 N to 1670 N for uncemented specimens and 760 N to 2750 N for cement addition. A similar twofold increase was also found for the KY nail.

These results would appear to validate the use of adjuvant bone cement in the repair of fractures in osteoporotic bone■

The Effects of Pulsed Galvanic Currents on the Healing of Soft Tissue Injuries

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Sponsor: National Institute of Handicapped Research

About 2 years ago, a Ph.D. candidate working in this lab reported that pulsed galvanic stimulation seemed to speed the healing of surgically divided Achilles tendons in rats. This past year, using tensile strength as the measure of healing, we confirmed those observations. Equipment limitations, however, precluded our ability to measure tensile strength above 1500 gms. Since this value is well below the load needed to break a normal or fully-healed tendon, we must currently limit our comments about healing to only the early stages. We hope ultimately to be able to appraise the long-term effects as well.

In addition to the tensile strength studies, we accumulated considerable electron microscopic data concerning the ultrastructure of normal tendon and tendon subjected to immobilization by casting or denervation. The observations, which suggest strongly that tendon is far from being an inert structure, hopefully will be reported at an upcoming conference in Boston. Basically, the findings are that immobilization leads to atrophy of collagen fibers. This suggests not only a turnover of collagen but the ability of tendon to meet the demands placed on it in much the same way that bone and muscle do.

Plans for the coming year include attempts to upgrade this project's materials-testing abilities (which will permit the monitoring of healing in more detail) and to continue with the electron microscope studies■

[See also **VI. Biomechanics, A. Joint Studies, 2. Lower Limb**, Biomechanics of Anterior Cruciate Repairs]

VIII. Properties of Muscle

Control of Muscle Protein Metabolism During Exercise

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

The broad objectives of this research are to study changes that occur in protein metabolism as a result of exercise and to establish the underlying biochemical mechanisms that bring about these changes. In research already completed, we have clearly established that an acute bout of exercise (either running or swimming) causes a decrease in the rate of muscle protein synthesis and increased rates of protein degradation in muscle and liver. Preliminary evidence from our lab and reports from other investigators suggest that an acute exercise bout also increases the rate of amino acid oxidation.

During the next granting period, we propose to further study the effect of an acute exercise bout on protein synthesis, protein degradation, and amino acid oxidation. To determine mechanisms involved in the decrease in protein synthesis in muscle, we plan to determine the effect of exercise on the various components of protein synthesis: charging of t-RNA, initiation of peptide synthesis, and peptide elongation. An experiment will be conducted to investigate whether an acute bout of exercise increases alanine production by the isolated epitrochlearis muscle. In addition, we plan to continue investigating the biochemical regulation of leucine oxidation in muscle during exercise■

Adaptation of Muscle to High-Resistance Exercise

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

The long-term objective of the proposed research is a fundamental understanding of neuromuscular plasticity. We will use as a model neuromuscular adaptation to high-resistance (weightlifting) exercise. Adult cats are operantly conditioned to flex their right wrist against increasing resistance in order to receive a food reward. This procedure has the advantage of inducing significant hypertrophy in the muscles of the right limb, while the muscles of the left limb can be used for comparative studies. Both increases in muscle fiber cross-sectional area (hypertrophy) and number (hyperplasia) have been shown to occur in response to weightlifting exercise.

The proposed study will determine the most effective exercise protocol for inducing muscle fiber hyperplasia and will investigate the importance of hyperplasia in the exercise-induced growth process. In the proposed study, the ultrastructural and histochemical features of exercised muscle fibers that are undergoing necrosis will be characterized. It is anticipated that this project will provide cytological evidence for the initiation of exercise-induced muscle fiber necrosis and help elucidate the significance of fiber turnover in adult muscle. Quantitative ultrastructural measurements of muscle fibers will be made to provide insight into the cytological reorganization that occurs in response to exercise. The physiological, histochemical, and morphological characteristics of motor units will be determined from forelimb muscles of trained cats.

These studies are made important by the observations of exercise-induced muscle fiber necrosis and fiber hyperplasia and will determine if these processes are independent of nervous system (motor) control. Little is known about the long-term effects of weightlifting exercise on muscle structure and function. This information is important in light of the findings of exercise-induced muscle fiber necrosis and hyperplasia and the increasing use of resistance exercise in this country as a component of health maintenance. These studies should should provide for a more informed and effective use of resistance exercise in the rehabilitation of patients suffering neuromuscular dysfunction■

Skeletal Muscle Adaptations Induced by Training

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

The greatly elevated energy demands placed on muscle during contractions often lead to a loss of adenine nucleotides (principally ATP) and a loss of contractile function. This phenomenon occurs during less severe contraction conditions in low-oxidative fast-twitch white muscle rather than in high-oxidative fast-twitch red muscle. Further adaptations induced by exercise training make the muscle more resistant to the ATP loss and fatigue. The return of ATP concentration during recovery occurs via the reamination of IMP using the amine donated from aspartate, but originating, in large measure, from the branched-chain amino acids (leucine).

Our proposed work will use the perfused rat hindlimb preparation to evaluate: (i) the contribution of branched-chain amino acid amine to the recovery of adenine nucleotides following intense contractions (specifically, we will determine the impact of leucine concentration in the physiological range), and (ii) during steady-state, long-term, moderately intense activity, where some deamination/reamination cycling may occur without extensive fatigue. The above-mentioned function may account for the increased branched-chain amino acid oxidation observed during and after exercise.

Using the same experimental system, we will assess the contribution of branched-chain acid oxidation to the energy demands of working muscle. We will test to see if it is minimal during mild exercise and increases during conditions when the amine donation function, mentioned above, should become more important (e.g., following intense fatiguing contractions). Further, the coupling of branched-chain amino acid oxidation to the purine nucleotide cycle will be evaluated with hadacidin, an inhibitor of adenine nucleotide resynthesis from IMP■

Myoelectric Assessment of Human Lumbar Muscle Function

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

The purpose of this project is to develop objective measures of lumbar muscle function for patients with low back pain. Techniques have been developed in this laboratory for measurement and analysis of the frequency spectrum of myoelectric signals obtained during exercise. Based upon information obtained from pilot studies, an isometric trunk exercise device has been constructed for use in collecting data.

Myoelectric data from the erector spinae and rectus abdominis muscles have been collected from a group of 15 young, healthy, normal adults performing isometric extension and flexion exercises on a simple back tester at load levels of 100 percent, 50 percent, and 20 percent of their maximum voluntary contraction (MVC) force. Another group of 10 healthy, young, normal adults (5 males and 5 females), and a group of 20 patients undergoing rehabilitation therapy for low back injuries, have been tested repeatedly on the newly developed back test device using similar protocols.

Mean power frequency slope measures of the myoelectric signal spectrum changes due to fatigue were shown to correlate with the load level. However, other factors for normals have been investigated that suggest that new measures could be developed to reduce this variability and increase the correlation between spectrum changes and load levels for fatigue trials. By normalizing the frequency slope to the initial frequency value, a linear decay measure (expressing slope as a percent decrease per minute) has been shown to improve the correlation. Linear decay measures of the first 20 seconds of a fatigue trial correlate well to measures of the full trial period, indicating that fatigue is measurable soon after load application. This suggests the feasibility of reducing testing time and patient discomfort.

One of the major problems of accurately measuring fatigue is the variability of the MVC due to subject motivation and neurogenic factors. MVC force measures, normalized for body weight, were found to correlate with slope measures obtained at 50 percent MVC, so that subjects who developed a higher force per unit body weight fatigued at a faster rate during the 50 percent trials. We are investigating the possibility of eliminating this variability by expressing the load level as a percentage of body weight, instead of MVC level. Using data obtained from normals, a strong correlation ($r \doteq 0.87$) is evident between the linear decay measure and load levels ranging from 20 to 120 percent of body weight. Pilot data suggest that it is possible to obtain frequency slope measures from patients exercising for short times at maximal effort. The slope measure is then compared to an appropriate normal data curve to find the corresponding load level that would be expected for the patient's age and gender.

Plans for future work involve acquisition of additional normal and patient data to fully test these hypotheses. Publications discussing these activities and findings in detail are in preparation■

Direct Measurement of Muscle Conduction Velocity and Fatigue in Neuromuscular Disease Patients

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Sponsor: National Institute of Handicapped Research

The specific objectives of this project are as follows: (i) to measure action potential conduction velocities along skeletal muscles during sustained isometric contraction leading to fatigue, (ii) to measure the power spectrum changes of the electromyogram that occurs during a fatiguing contraction, and (iii) to correlate the conduction velocity measurements with those of the power spectrum. The above measurements will be performed in normal individuals and in subjects afflicted with neuromuscular disease.

As part of this project, a noninvasive procedure will be developed to measure muscle conduction velocity continuous with time. The procedure involves the placement of two sets of wire electrodes over the biceps brachii muscle and recording the electrical activity during a strong contraction. A minicomputer will compute and plot the velocities, as well as the mean frequency of the power spectrum as a function of time, during the course of the contraction. These analyses will be performed for at least two different intensities of contraction in each subject.

Twenty normal adult individuals, male and female, and approximately 20 patients with signs of myopathic disease will be tested■

Origin of Limb Position and Movement Signals in Humans

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

This project will study how the senses of static limb position and limb movement originate from sensory receptors in skin, joint, and muscle in humans. The tests use matching one limb or digit to another, and detecting movements or misalignments. To distinguish movement sense from position sense, we measure how rate of movement alters subjects' ability to sense displacements. Using healthy adult volunteers, we first establish baseline performance levels, then selectively eliminate sensory inputs from skin, muscle, or joint and measure the resulting deficit, if any. Some tests will use patients having a complete rupture of the Achilles tendon to check the validity of our nerve block experiments.

Our goal remains to test the hypothesis that muscle spindles provide the necessary and sufficient sensory input for position sense, with the hand providing a possible exception. We now have clear evidence for both propositions and plan to elaborate and document our findings over this next year.

Finally, we will test the importance of gamma control of muscle spindle activity for position sense with: (i) relaxed muscles, (ii) partial (gamma) block of motor nerves, and (iii) nerve recordings from spindle afferents in humans noting changes (that reflect gamma activity) during position discriminations.

Knowing the sources of the limb-position and movement detectors, and more about coding and fusimotor control, we can then do meaningful experiments with animals■

Surface Electrode for Detecting Myoelectric Signals

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Sponsor: Liberty Mutual Insurance Company

Many aspects of muscle activity during contraction may be observed by analyzing the myoelectric signal originating from the muscle fibers. The myoelectric signal can be detected by placing metallic electrode contacts on the surface of the skin directly above the muscle. This is a noninvasive recording technique and therefore well suited for a variety of laboratory and clinical observations of muscle status. For accurate signal analysis, detection of myoelectric activity must be reliable and consistent.

Designing an electrode to record this activity is not an easy task. The amplitude of the myoelectric signal at the skin's surface is extremely small, typically less than one millivolt. External interference from power lines and fluorescent lights can easily mask or distort the desired signal. The problems can be further compounded by poor electrical contact with the detection surface due to dry or oily skin. It is common, therefore, to place electrically conducting pastes and gels between the skin and electrode.

To minimize these effects and maintain consistent results, we have developed a standard surface recording electrode which does not require the use of conducting pastes and gels. Two configurations of this pasteless electrode have been designed. One configuration consists of two signal detection surfaces formed from 3 mm diameter metallic disks spaced 1.0 cm apart, surrounded by a metallic ring which serves as an electrical ground. This version is especially suited for probing areas of myoelectric activity from large or small muscle groups. In the other configuration, the detection surfaces are formed by two parallel 1.0 cm long metallic bars spaced 1.0 cm apart. This version is useful for measuring signals related to localized muscular fatigue.

Both configurations are mounted directly on small epoxy packages containing high-impedance, low-noise differential preamplifiers. The high-impedance feature minimizes the effect of dry or oily skin. The differential preamplifier reduces the effect of unwanted electrical interference. The preamplifier also amplifies the signal and filters frequency components outside the range of interest. This process improves the signal-to-noise ratio of the system.

We have found that these surface electrodes have the mechanical and electrical stability necessary for reliable and consistent low-noise myoelectric recordings, and we now use these electrodes in all the surface myoelectric recordings in our laboratory. We hope that this standard will be adopted by other researchers■

The Myoelectric Signal Decomposition Technique

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Sponsor: Liberty Mutual Insurance Company

During the past several years, we have developed a system of studying the behavior of muscle units known as motor units, which consist of individual functionally distinct groups of muscle fibers within the muscle. With this system we can extract from the muscle information which helps us to understand the nature of the control schemes that the central nervous system uses to govern muscle contractions. Our system works in three phases: (i) the data signal acquisition phase, (ii) the data preprocessing and decomposition phase, and (iii) the analysis phase. Improvements have been made this year in all these phases.

The data signal acquisition phase is managed by a computer-controlled data collection system. We have modified this system to allow monitoring and tracking of two-dimensional force trajectories. A newly constructed restraint device can measure two force vectors in a plane. The outputs of the force transducers are connected directly to an analog-to-digital converter on the minicomputer that controls the data collection. The recorded forces themselves may be displayed on a screen, or the computer may generate force trajectories and display them simultaneously with the recorded forces.

We have improved the second phase, preprocessing and decomposition, by capitalizing on the greater computing power of the VAX computer over the PDP-11/34. New features have been added to the decomposition program to make it easier to use. We now have the capability of decomposing from up to 19 simultaneously active motor units. Finally, we have added an option that handles time synchronization between records generated simultaneously from different muscles.

For the analysis phase, we have added a set of programs to allow rapid cross-correlation between motor-unit firing rates and computer storage of the cross-correlation results. A program has also been developed to analyze any instantaneous interaction between the muscle fiber activity.

Overall our improvements in the system have expanded the range of motor-control aspects that we can examine with the decomposition technique; at the same time they have increased the ease of our experiments and decreased the time for data processing■

The Common Drive Concept

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Sponsor: Liberty Mutual Insurance Company

The central nervous system modulates muscle force either by varying or recruiting the number of motor units which contract, or by varying the firing rate at which they are activated to contract. Thus, when we begin to understand the strategy or strategies which the nervous system uses to control motor units and to generate and modulate the force of a muscle, two central questions arise.

1. Is there a strategy or rules which govern the process of motor unit recruitment?

2. Is there a strategy or rules which govern the behavior of firing rates of active motor units?

The first question has received considerable attention. The second question has received very limited attention since experimental procedures are so technically complex. Our decomposition technique has removed some of the technical barriers.

Our investigations into the firing rates of motor units have consistently demonstrated a universal property of firing rates: the firing rates of all concurrently active motor units are modulated in unison when viewed as a function of time or force. We have termed this property the common drive. Its existence indicates that the nervous system does not control the firing rates of motor units individually, but instead it acts uniformly on a group of motor units.

We are convinced that our observations reflect a basic physiological control scheme of the nervous system. We have seen common drive in hundreds of muscular contractions of various kinds, in over a dozen muscles in the upper and lower limbs. We have seen it in every one of two dozen subjects, including sedentary normal individuals, Olympic-caliber athletes, and accomplished pianists. Common drive appears to be a truly universal property.

Common drive is important because it demonstrates, by example, that the central nervous system (the brain and spinal cord) is not involved in supervising the details that govern the behavior of individual motor units during a contraction. By implication, the central nervous system is concerned with more gen-

eral control schemes. Several other observations made in our laboratory support this conclusion. Common drive also gives us an avenue for studying the communality of different muscles involved in a task.

The Control of Individual Muscles: Relationship Between Firing Rate and Recruitment

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Sponsor: Liberty Mutual Insurance Company

Firing rate and recruitment, the two modes of motor unit control, are used differentially between contractions requiring slow versus fast rates of force production, and specific muscles employ different degrees of one or the other of the two modes. Our past experiments have documented an interplay between motor-unit recruitment and firing rates; recruitment of a new motor unit may reduce the firing rates of previously activated motor units.

We have now identified the likely pathway of action in this effect. At least partially, the pathway may involve some specific sensors within the muscle which are responsible for the stretch reflex (muscle spindle and Golgi tendon organs) and possibly some specific nerve cells in the spinal cord (Renshaw cells). The logic of this possibility is that, when a new motor unit is recruited, it cannot contribute less to the total muscle-force output than its characteristic quantal value. Thus, when the motor unit is recruited, a step increase would occur in the total output force unless simultaneously the contributions of the already active motor units are reduced, via a decrease in their firing rates.

The significance of this in terms of motor-control strategy is that a smoother output force may be achieved via peripheral nervous system circuitry, lessening the amount of detailed supervision that the central nervous system has to perform. (An article is being prepared for publication.)

Synchronization of Motor Unit Discharges

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Sponsor: Liberty Mutual Insurance Company

Synchronization is the tendency for two muscle fibers, each connected to separate nerves, to contract at the same time, or at almost the same time, more often than we would expect if the two fibers were actually contracting independently. During the past 50 years, numerous controversies have surrounded the very existence and usefulness of synchronization. Factual investigations of voluntary contractions have been limited due to limitations in detection and analysis techniques. Our decomposition technique removed some of these limitations. Having complemented this technique with an analytic technique called the conditional intensity, we can now objectively observe and measure synchronization.

We have observed synchronization between fibers within a muscle both during rapid-force, varying contractions, and during constant-force, non-fatiguing contractions. The degree of synchronization is greater during the rapid-force, varying contractions. We have not observed synchronization of fiber contractions between antagonist muscles such as flexion-extension pairs.

Several possible sources and causes of synchronization have been identified. We are now attempting to demonstrate a causal relationship between the sources and the observed phenomenon. We expect that our systematic and accurate approach will provide some explanations that have eluded us in the past.

The Control of Antagonist Muscles During Contraction

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Sponsor: Liberty Mutual Insurance Company

We are working to clarify the control mechanism of antagonist muscles during initiation and continued production of force during voluntary contractions.

Using the decomposition techniques, we acquired and processed the myoelectric signal from two forearm antagonist muscles, the long flexor and the long

extensor muscles of the thumb. Our experimental procedure aimed to relate the firing-rate behavior of motor units in the two antagonist muscles under various conditions.

The experiments showed that during pure joint stiffening the two cocontracting antagonist muscles are controlled by the nervous system as if they constituted an individual muscle; this we inferred from observing that the motor units of antagonist muscles display in-phase firing-rate fluctuations. Conversely, during alternating flexion and extension contractions, the two antagonist muscles are reciprocally activated; when the firing rates of motor units in one muscle decrease, they increase in the antagonist muscle.

These results are consistent with the concept that the central nervous system has two separate control schemes of coactivation and reciprocal inhibition, and that the two schèmes may be used in different ways to control the torque or stiffness of a joint. These results further support the notion that the central nervous system does not control motor units individually during a muscle contraction and imply that muscles acting on a joint may not be controlled individually. (An article is being prepared for publication.)■

The Control of Synergist Muscles During Contraction

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Sponsor: Liberty Mutual Insurance Company

Synergist muscles act in concert and have an additive force contribution during a specific function. Since the body's musculature is composed of both groups, antagonist muscles and synergist muscles, it is important for us to complement our work on antagonist muscles with studies of synergist muscle control.

The muscles under study are two forearm muscles which control the extension of the wrist, the ulnar extensor muscle of the wrist, and the long radial extensor muscle of the wrist. We first had to construct a new apparatus to stabilize the forearm during contractions and to couple the hand to force transducers. We also designed methods for measuring force and for video communications with subjects. To detect, record, and analyze the muscles' signals, we used the quadripolar needle electrode described in our 1982 Activities Report and our computer-controlled system for myoelectric data acquisition, decomposition, and analysis. Initial results with three subjects show some interesting relationships to our results from experiments on antagonist muscles.■

Muscle Fatigue and the Myoelectric Signal

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Sponsor: Liberty Mutual Insurance Company

The frequency spectrum of the myoelectric signal detected with surface electrodes shifts toward the low-frequency end during sustained muscle contractions. High-frequency components decrease while the low-frequency components increase in amplitude. Various studies during the past two decades have searched for the cause of this frequency shift, whether it originates from the physical properties of muscle fibers such as their conduction velocity or from control properties such as firing statistics.

We investigated this question by deriving mathematical expressions for the power-density spectrum of the myoelectric signal. Separate functions expressed the individual effects of the firing statistics and of the shape of the motor-unit action potentials. Experiments and detailed data analysis were performed on sustained muscle contractions.

Our results strongly suggest that the effect of firing on the power-density spectrum of the myoelectric signal is significant, but that firing statistics alone cannot account for all of the frequency shift during sustained contractions. Therefore, both the control properties and the physical properties of muscle fibers are implicated.

A detailed review of the literature and our work suggested that the frequency shift could be monitored by tracking the median or the mean frequency. Mathematical analyses and available empirical results yield the logical explanation that a series of biochemical events, muscle architecture, physiological properties, and signal propagation properties can explain the frequency shift during sustained contractions. This explanation also supports the idea that the frequency shift can be used as an objective measure of localized muscle fatigue.■

Muscle Fatigue Differences Due to Handedness and Gender

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Sponsor: Liberty Mutual Insurance Company

Hand dominance offers a model, within the same subject, of lifelong endurance training in some muscles (of the dominant side) and comparatively less training in others (of the nondominant side). We exploited this model by testing the median frequency of the myoelectric signal of the muscle that controls the index finger. We tested the signal in both of the hands of 18 right- and 17 left-handed normal young subjects, 16 men and 19 women. The median frequency of the myoelectric signal, which is directly related to the intramuscular conduction velocity, was measured during constant force contractions at different maximal voluntary contraction levels.

Previous results had shown that the higher the contraction level, the faster would be the decreases in the median frequency of the myoelectric signal and in intramuscular conduction velocity. In this study, our right-handed subjects showed a significantly greater decrease in the median frequency of the nondominant-side muscle than in the dominant-side muscle. In the left-handed subjects, however, no measurable difference appeared between the median frequency of the dominant and nondominant sides.

These results suggest that the dominant-side muscle is less fatigable than the nondominant-side muscle in right-handed but not in left-handed subjects, adding support to the notion that left-handed subjects are more ambidextrous. These results also imply a possible difference in the muscle fiber composition or blood-vessel arrangement (vascularization) between comparable muscles on the two sides of right-handed subjects. (No measurable differences were found between male and female counterparts.)

One practical implication of the difference we found in right-handed subjects is that isomorphic assumptions about a right-handed individual's right or left side may lead to erroneous conclusions when one-sided injuries are being evaluated. (A manuscript is being prepared for publication.)■

The Muscle Fatigue Monitor

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Sponsor: Liberty Mutual Insurance Company

For several years we have been developing the Muscle Fatigue Monitor (MFM), a device that estimates automatically and on-line the median frequency of the myoelectric signal. The MFM will help us to obtain objective measures of localized muscle fatigue. This year we have implemented an entirely new version.

The MFM now contains two independent plug-in data channels for processing the median frequency information in fatigue measurements. The two-channel arrangement enables us to evaluate simultaneously a two-muscle system's fatigue process. To make the new data acquisition system compatible with other devices, we installed an RS-232 serial interface. This hardware allows us to write or store programs or data using the center's VAX computer system.

The new device is highly flexible. Each user may tailor the system to a particular experiment by selecting various stored programs. Preliminary software programs have been written to control the system, to sample data, and to plot results from the median-frequency channels.

We plan to generate and store more specific and detailed software in a program library on the VAX. Plans are in progress to expand the scope of the MFM data acquisition system to include plug-in hardware modules for measuring the conduction velocity of a muscle and the range of motion of a subject's limb. With these new modules, the system will be able to monitor and record data from more complex muscle fatigue experiments. (A detailed description appears in our paper, "Muscle Fatigue Monitor (MFM): Second Generation," which has been submitted for publication.)■

The Estimation of Muscle Fiber Conduction Velocity

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Average conduction velocity has been conventionally measured by cross-correlating two surface waveforms obtained from different locations along the muscle. This conventional technique uses a configuration of these spatially distinct electrode sites on the muscle surface which in turn yield two differential sources.

In our experiments, however, we ascertained that this configuration still gave erroneous conduction velocity values from some muscles. Some of the cross-correlated signals exibited almost a zero time delay, probably due to the fact that muscles are electrically nonhomogenous and signals do not exhibit the same time delay on different axes. To overcome this problem, we added a fourth electrode and inserted another layer of differential amplifiers in the recording arrangement. The new technique correctly estimated the average conduction velocity in all subjects tested.

We are now constructing a device to implement our innovative method. Prototype circuitry has been fabricated, using the 4-electrode configuration. The device will compare the two output signals using cross-correlation and will then compute the conduction velocity of the muscle fibers. Once refined, the circuitry will be incorporated into a new channel in the new MFM data acquisition system. With the existing median-frequency measurement channels and the new muscle fiber conduction velocity channel, we will be able to compare directly each method of fatigue measurement. We expect that these two noninvasive methods will improve the objective assessment of localized muscular fatigue■

IX. Ligaments and Tendons

Ligaments Proteoglycans and Interactions with Collagen

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

Normal skeletal function is determined, to an important extent, by the integrity of ligaments and tendons. Several orthopaedic diseases (e.g., congenital clubfoot, idiopathic scoliosis, congenital hip dislocation) involve either abnormal contraction or relaxation of ligaments, while in other conditions, abnormalities of ligamentous structures are suspected. Ligament injuries are common in many active sports and in situations involving strenuous physical exercise. However, therapeutic regimes prescribed during recovery from these injuries are mostly empirical, since the molecular organization of ligaments and tendons is poorly understood. In particular, the interactions of collagen with proteoglycans and with other components of the intercellular matrix, and the function of these interactions in determining the properties of the tissues, are largely unknown.

We plan to study, using in vitro model systems and electron microscopy, the effect of well characterized proteoglycans, which we have extracted from bovine and canine ligaments, on the kinetics of formation of collagen fibrils and on their properties. We also plan to study the effect of the presence or absence of proteoglycans on the maturation of collagen and formation of the cross-links. Using affinity chromatography methods, we will study the binding of proteoglycans to different collagen types. By enzymatically and chemically modifying the proteoglycans, we hope to clarify which parts of the molecules are more important in the interactions. We also plan to purify and characterize some matrix glycoproteins which have been detected in animal ligaments during preliminary work and to study their possible interactions with other matrix macromolecules.

The long-term goals are: (i) to study molecular defects which may be at the basis of the pathogenesis of disease processes involving contraction, relaxation, or loss of functional strength of ligaments; and

(ii) to study molecular changes occurring during exercise and aging. Toward the partial fulfillment of these goals, we will study human ligaments obtained at the time of corrective surgery from patients with idiopathic scoliosis and congenital clubfoot. We also will examine their collagen, proteoglycan, and glycoprotein content, types, and extent of collagen cross-linking■

Development of Synthetic Replacement Fibro-Osseous Pulleys

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Sponsor: National Institutes of Health
(National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases)

The fibro-osseous pulleys of the digital flexor mechanism may be adversely affected by trauma or disease, resulting in bow-stringing of the tendon, loss of digital flexion, and poor joint motion. Replacement of these pulleys with biological or synthetic materials would be clinically useful to the surgeon (i) when the pulley is traumatically absent, (ii) at surgical tendolysis when the pulley also is incorporated in the fibrous adhesions, and (iii) at tendon grafting when the pulley is incorporated in the fibrous adhesions. Previously used synthetic materials (Dacron, Silastic) did not have biomechanical properties that were adequate for the substitution of pulleys in the human hand. Replacement pulleys must be technically easy to place, compatible with surrounding tissues to minimize scar formation, and have immediate maximum strength so that mobilization of the digit can be instituted in the immediate postoperative period.

We are developing and evaluating a synthetic pulley in the nonhuman primate that has anatomical characteristics similar to the human. We are pursuing a relatively long-term study in the monkey to determine if a synthetic pulley made of woven monofilament nylon (Nitex) is comparable to a replacement pulley made of biological materials. The pulleys are being evaluated with respect to (i) the limitation to tendon gliding by restrictive adhesions, (ii) the functional competency of the replacement pulley, (iii) the integrity of the flexor mechanism structures (pulley, tendon, bone) and (iv) the biomechanical properties of the pulley in relation to the intact mechanism■

X. Arthritis

Assessment of Self-Care Programs for Arthritis Patients in Rural Settings

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Sponsor: National Institute of Handicapped Research

This is a study to determine the effectiveness of self-care instructions and methods in the management of arthritis in patients living in rural areas. The locale for the study comprises several counties in the Shenandoah Valley of Virginia.

Work is progressing according to schedule■

Arthritis Rehabilitation Unit

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A five-bed rehabilitation unit to determine the effectiveness of an inpatient rehabilitation program for arthritis patients has been created. The team responsible for this project is working closely with the Virginia Department of Rehabilitative Services■

XI. Low Back Pain

Chronic Low Back Pain Attitude Survey

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This project is being conducted as a complement to the regular clinic services provided by the Pain Management Clinic, and is proceeding on schedule.

Low Back Pain Prevention, Treatment, and High-Risk Inventory Development

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Of special interest in this project is the application of experimental programs to the University Hospital Employees. The nurses were identified as the group with the most time lost from work owing to back pain, and a comprehensive program designed to reduce the incidence of low back problems has begun. The program also has been extended to hospital employees in other types of work.

Low Back Pain Studies

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Mission—The overall mission of the Vermont Rehabilitation Engineering Center is to improve our understanding of low back pain (LBP) diagnosis and to rehabilitate LBP sufferers, through the collaborative efforts of clients, engineers, clinicians, and multiple health care providers in rehabilitation research. Successful diagnosis and rehabilitation of LBP sufferers requires precise, reproducible, and quantitative methodologies. Because of the extraordinarily high prevalence of low back complaints, even small gains can have a very large impact in terms of the numbers of individuals affected by LBP and the degrees to which they are disabled by it.

Objectives—Specific objectives of current research projects at the center are:

1. To develop an objective, reliable, and generalizable data base for the assessment of LBP sufferers, which also may be applied to all socioeconomic groups, including minorities and traditionally under-represented groups.
2. To develop an objective, reliable method for the assessment of rehabilitation effectiveness in LBP disease, including measures of cost, which is applicable to the same general population.
3. To develop methods and devices to quantify LBP and the potential for rehabilitation by such means as biomechanical measurements, psychophysical methods of LBP quantification, intracompartmental pressure, intra-abdominal pressure, and EMG.
4. To define and further understand new or ill-defined causes of LBP (for example, segmental instability, or compartment syndrome).
5. To design new orthotic systems applicable to the rehabilitation of LBP sufferers, such as electrical stimulation (to increase strength and/or to control pain), braces, corsets, and combined brace-stimulation systems, and to test the effectiveness of these systems in the rehabilitation of LBP sufferers.
6. To develop optimal seating systems for both static and vibrational environments to reduce the risk of developing LBP, as well as part of the strategy for preventing recurrent episodes of LBP.
7. To evaluate promising exercise programs applied to specific subgroups of LBP sufferers.
8. To develop a methodology for the evaluation of the worker and the workplace as a means of occupational rehabilitation of LBP sufferers.
9. To develop local, regional, and national LBP educational programs for the public-at-large, including traditionally under-represented socioeconomic and minority groups as well as health care professionals and engineers.

XII. Respiration (Muscular Dystrophy)

Inspiratory Muscle Fatigue as a Cause of Respiratory Insufficiency in the Muscular Dystrophies and other Neuromuscular Diseases

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Sponsor: National Institute of Handicapped Research
Muscular Dystrophy Association

The inability to meet oxygen demands during work levels because of ventilatory muscle fatigue can result in a decrease in the efficiency of a rehabilitation program. Results from isotonic exercises to increase respiratory muscle endurance have been equivocal.

The use of isokinetic (resistive) exercise has not been fully explored as a technique for respiratory muscle readaptation. Consequently, we have devised an isokinetic exercise program for inspiratory muscles to be used in patients with neuromuscularly-induced weakness of respiratory muscles. Improvement will be assessed in terms of isometric pressure generation, peak airflow, and maximum breathing capacities■

Respiratory Load Compensating Mechanisms in Muscular Dystrophy

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Although it is well established that respiratory problems are a leading cause of disability and death in the muscular dystrophies (MD), the mechanisms underlying respiratory insufficiency remain unclear. In light of recent work identifying respiratory sensory and central abnormalities, we propose that these problems represent a combination of respiratory sensory, central, and motor dysfunctions.

It is proposed to test this hypothesis using the loaded breathing technique in which external mechanical loads are imposed noninvasively at the mouth to impede inspiration. Loads disrupt the usual relationship between the effort and corresponding movement of the respiratory system and, in doing so, activate those mechanisms that normally defend ventilation in the face of naturally occuring loads. This technique thus assesses the combined action of respiratory sensory, central, and motor functions during spontaneous breathing.

Despite these obvious advantages, the study of loaded breathing in MD has been precluded in the past by: (i) the lack of an adequate analytical method of identifying the action of load-compensating mechanisms; and (ii) the lack of an adequate normal standard. As is described in the literature, we have overcome both these problems by deriving a mathematical model to identify load-compensating mechanisms, and by applying it to interpret data obtained from large groups of normal and quadriplegic people. This information will be used to: (i) investigate the relationship between load-compensation and severity of disease; (ii) evaluate residual load compensation; and (iii) quantify the deficit in load compensation in groups of subjects with MD. We believe these new findings will be of fundamental importance in the understanding of ventilatory regulation in the muscular dystrophies and, ultimately, in the design of appropriate rehabilitative regimens to alleviate the tragic respiratory problems associated with these diseases■

XIII. Sensory Aids

A. Blindness and Low Vision

1. General

Demonstration of a Low Vision Aid Clinic as an Employment Enhancement Technique

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Research Problem Addressed—The purpose of this study is to determine whether providing a low vision aid (LVA) to a partially blind person who is employed in a protected work setting will enhance that person's employment as measured by productivity and self-satisfaction.

Methodology—A single subject research design is being employed to examine the use of LVAs by 50 subjects randomly selected from the partially blind workforce of the Mississippi Industries for the Blind (MIB). These subjects were serially screened for LVA prescription by (i) complete medical and extraocular examination, and (ii) Goldman field examination. Following LVA prescription as required for maximum efficiency in his/her work environment, specific training was provided to encourage use of the LVA on the job.

Progress to Date—Forty-eight randomly selected subjects were seen in the LVA clinic. Of the 48, 18 (mean age = 38.72; S.D. = 9.45) were prescribed LVAs (≥4 + add). Fifteen (mean age = 32.07; S.D. = 10.94) were prescribed optical aids (OA) (≤4 + add), and 15 (mean age = 42.06; S.D. = 9.48) received no aid because visual functioning could not be improved through the use of an aid. Analyses of payroll data, absentee rate, responses on the Minnesota Satisfaction (MSS) questionnaire, and other interview data are being collected 30 days, 6 months, and 12 months after receipt of the prescription. Preliminary analyses show that the LVA and OA groups have responded favorably to the aids. The LVA and OA groups questioned said they could work better with the aids and had little or no trouble using them. Eighty percent stated their aids neither decreased mistakes nor increased income, while 20 percent said their aids increased income and helped them make fewer mistakes■

Industrial Services Program Model for Sheltered Workshops for Legally Blind Workers

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Research Problem Addressed—Does the Industrial Services Program model (ISP) enhance the employability of blind or partially blind persons? This research project addresses two questions:

1. Does the ISP increase the productivity of blind workers who are newly employed in a protected industry?
2. Does an adapted ISP increase the productivity of blind workers who are newly employed in a competitive industry?

Methodology—A multiple time series design has been used to investigate the efficiency of a specific ISP on the performance of 12 of 45 blind subjects. The experimental group was 12 persons hired by Mississippi Industries for the Blind (MIB) who had received preemployment training using the adapted ISP. The control group consisted of the last 45 employees hired by MIB prior to the initiation of in-plant ISP training. MIB, an affiliate of the National Industries for the Blind, has a work force of approximately 300 employees, 200 of whom are blind.

Progress to Date—Twelve experimental subjects of the planned 33, who had not previously been employees of MIB, have been hired since February 1981. All have completed ISP training. Attendance data, the MSQ, and the MSS have been collected 7, 21, 60, and 90 days following the completion of ISP training. Eight of these subjects remained employed at MIB for

the full 90-day period; four terminated prior to completion.

FY 1985 Activities—An interim progress report will be published. During the upcoming year, ISP projects will be initiated in competitive industries in the state of Mississippi. Research will focus upon the performance of blind and partially blind research subjects in preemployment training classes.

Assessment of Current Career Development Intervention Services and the Needs of Blind and Severely Visually Impaired Individuals

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Research Problem Addressed—The purposes of this project are (i) to assess current career development services for blind, partially blind, and severely visually impaired persons, and (ii) to assess the career development service needs of these persons.

Methodology—The research design used will determine the extent to which current career development intervention strategy services meet the career development needs identified by: blind students, their teachers, and parents; rehabilitation agency administrators and counselors; and adult consumers and parents of consumers randomly selected from special populations.

Progress to Date—Questionnaires were sent to persons in the following groups: students, parents, and teachers in grades K, 3, 6, 9, and 12; agencies; counselors; adult consumers; and, parent consumers.

FY 1985 Activities—Research efforts during the upcoming year will be focused upon data analysis. Career development needs will be identified.

Functional Outcome for Blind/Severely Visually Impaired Clients of State Rehabilitation Agencies

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Research Problem Addressed—The purpose of this study is to identify factors that predict the functional outcome of services provided to blind clients of selected state rehabilitation agencies. The research question to be answered is: To what extent can the functional outcome of blind individuals closed "26" or "28" by state rehabilitation agencies be predicted by a) services received, b) client characteristics, c) county economic conditions, and d) proximity to rehabilitation services?

Methodology—Multiple discriminate analysis is being used to assess functional outcomes and related characteristics of 619 blind and partially blind persons whose cases were closed "26" or "28" by rehabilitation agencies in Florida, Kansas, Mississippi, and Ohio. Subjects were selected at intervals in proportionate numbers according to rehabilitation case closures, from the four state agency populations in FY 1978, 1979, and 1980.

Stepwise multiple discriminate analysis is being used to develop a multiple discriminate function to predict the work status outcome criterion variable. This process allows the computation of the best possible combination of predictive variables associated with the functional outcome group. Other analyses will be made as deemed appropriate.

Results to Date—The data are undergoing analyses. Regression equations, discriminate function analyses, and other statistics have been computed.

FY 1985 Activities—Analysis of data collected for this project will be completed during the coming year. A technical report will be available from the Rehabilitation Research and Training Center in Blindness and Low Vision.

Illumination Level and Color Contrast Studies

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Research Problem Addressed—The purpose of this project is to determine whether manipulating the illumination level and altering color contrasts significantly increase productivity and comfort of partially blind production workers. This project addresses three questions:

1. To what extent does increasing or decreasing illumination affect the performance of partially blind production workers on a task performed visually?
2. To what extent does varying color contrast affect the performance of partially blind production workers on a task performed visually?
3. To what extent does optimizing illumination of work site and color contrast of work site materials increase the productivity and comfort of partially blind production workers?

Methodology—Fourteen subjects, half of whom use powerful low vision aids prescribed in RRTC/BLV project R-1 (Demonstration of a Low Vision Aid Clinic as an Employment Enhancement Technique) were tested with respect to various illumination levels and color contrast conditions to determine the specific levels of the variables that maximized their productivity and comfort. The job site of each subject was then modified in accordance with optimum illumination and color needs.

The design was an A-B-A-C-A-D-A single subject withdrawal design, with A representing non-treatment phases, and B, C, and D representing light-only, color-only and color-plus-light modification phases, respectively. Before and after each modification (or treatment) phase, the modifications were withdrawn, resulting in non-treatment phases alternating with treatment phases. The dependent measures were productivity rates and comfort ratings.

Progress to Date—At the test site an optimum level of lighting and color contrast was identified for each subject. Results of visual testing indicated that, for some individuals, specific lighting conditions and color contrasts were related to better performance. There were considerable individual differences in terms of what constituted optimum conditions for each subject and to what degree optimum conditions facilitated visual performance.

Production rates before and during the treatment sequence were highly variable; some exhibited higher production rates related to one or more of the modifications, while others did not. Of those who did, better performance was related to the light modification and not to color.

Subsequent to collection of productivity data, subjects were asked to respond to comfort questionnaires. The majority of subjects responded favorably with respect to all modifications.

FY 1985 Activities—Analysis of data collected during this project has been completed. A technical report of findings will be available from the Rehabilitation Research and Training Center in Blindness and Low Vision■

Development of Electromechanical Vocational Assessment Technology for Finger Dexterity and Hand/Foot Coordination

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Research Problem—The purpose of this study is to determine the reliability and validity of four preemployment evaluation and training electromechanical work task units (EVAT). The question to be answered is: Are each of the six electromechanical work task units reliable and valid preemployment assessment technologies for blind or partially blind production employees?

Methodology—A test-retest over time design was used on 30 subjects drawn from the following rehabilitation facilities and sheltered workshops: Mississippi Industries for the Blind, Jackson, Mississippi; Addie McBryde Rehabilitation Center, Jackson, Mississippi; Royal Maid Association for the Blind, Hazlehurst, Mississippi; Regional Rehabilitation Center, Tupelo, Mississippi; Royal Maid Association for the Blind, Tupelo, Mississippi; and, Louisiana Association for the Blind, Shreveport, Louisiana.

Background data were collected on all subjects tested. Data included date of birth, medical and psychological information, work history, and level of

education. Additional information included relevant vocational evaluation and assessment scores: Valpar, WRAT, IQ, and the Pennsylvania Bi-Manual Dexterity Work Sample. For individuals who were employed at the time of testing, job analysis and supervisor ratings were obtained.

Reliability levels indicating test accuracy over time are being established by computation of coefficients of stability obtained through test-retest procedures. Product-moment correlation is the primary method used. A standard error of measurement also is being determined.

Data collection procedures have been arranged to minimize practice effects on test-retest reliability; the length of interval between testing periods, and the lack of intervening training activities, tend to reduce the impact of practice on the reliability measure. Preliminary results indicate that the reliability of the Five Finger Dexterity Work Task Unit is quite high. This appears to hold true even when the retest interval is varied.

Progress to Date—At this time all testing has been completed. Efforts are being made to determine the accuracy of the background data collected from personnel folders and facility client files. These efforts have resulted in the addition of some medical information and vocational assessment scores.

FY 1985 Activities—Data analysis on this project will be completed during this year. A technical report of findings will be available from the Rehabilitation Research and Training Center in Blindness and Low Vision■

Vocational Assessment of Blind, Partially Blind, and Severely Visually Impaired Persons: Adaptation of the Vocational Education Readiness Test

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Research Problem Addressed—In connection with training programs in the fields of auto mechanics, electrical wiring, and industrial sewing, the research question to be answered can be stated as follows: Are each of the adapted Vocational Education Readiness Tests (VERTs) reliable and valid indicators of a blind or partially sighted person's aptitude for success in a specific training program?

Methodology—Each VERT test was screened to determine the elements requiring vision. The training samples were then constructed at the field work site. Project personnel have been and are receiving training and consultation in use of the training samples and recording of project data. The training sample data being collected at the field test site serve as the basis for revisions to the training samples or training sample procedures.

A test-retest over time design is being used. The tests are being administered to present trainees and employees at the Royal Maid Association for the Blind and the Regional Rehabilitation Center, both in Tupelo, Mississippi. Participants have been selected randomly from a group of volunteers in each location. There have been 15 individuals tested and retested on each work task. Sighted standards and norms have been developed for blind and legally blind individuals. Baseline data have been collected for all training samples.

Reliability levels will be established by computation of coefficients of stability obtained through test-retest procedures. Retests will be conducted within a 90-day period. No additional training on the work sample will be conducted. Practice effects will potentially impact any performance-based assessment technique, but here the length of the interval between testing periods and the absence of training activities reduce the impact of practice on the coefficient of stability.

Validity will be determined in two ways. Concurrent validity will be established by (i) correlating training task scores with the subjects' scores on other vocational evaluation systems for which similar tasks are available, and (ii) by comparing the job analysis of the job on which the training sample was designed with the resulting training sample. Other data to be gathered on the client data form will include visual disability and information on secondary disabilities.

Progress to Date—Reliability and validity data are being collected for adapted VERT. Fifteen subjects have been tested and retested on adapted auto mechanics and adapted electrical wiring. Criterion tests (VALPAR 2) for validity, as well as additional work task adaptations, are in process.

FY 1985 Activities—This research design will be employed to establish the reliability and validity of the industry sewing and quantity food tests. The auto mechanics test will be field tested in various sites throughout the country■

Training Opportunities Profile for Visually Impaired Persons: (TOP-VIP)

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Research Problem Addressed—The intent of this project is to develop a series of assessment materials that can be used in vocational evaluation centers to assess the capabilities of blind persons to enter training in one of the five following job clusters: (i) computer programming; (ii) counseling/social work; (iii) management; (iv) sales; and, (v) allied health.

Methodology—Technical and professional job clusters were identified which met the conditions of (i) a high number of employed or in-training blind persons, and (ii) forecasts indicating that employment possibilities are expected to continue for the foreseeable future.

The information concerning the tasks involved in each of these job clusters and information concerning the characteristics of persons employed to perform these tasks is being collected. Information concerning the job task and manpower requirements is being obtained from literature and interviews with sighted and blind workers, as well as from trainers of blind and sighted persons in the respective job areas.

This information will be used in constructing assessment materials for each job cluster. The assessment materials will be criterion referenced for use in career decision making by blind persons.

Results to Date—Work Samples and Visually Impaired Persons: A State-of-the-Art Review and Resource Manual will be published in 1984■

Prevocational Work Ability and Success Acquisition Training of Deaf-Blind and Other Multiply Visually Handicapped Individuals

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Research Problem Addressed—This project is based upon preliminary findings of RRTC/BLV research project R-6, Development of Electromechanical Vocational Assessment Technology (EVAT) for Finger Dexterity and Hand/Foot Coordination. Those EVAT units found to be reliable assessment technologies of finger dexterity and hand/foot coordination will be adapted to determine whether they may be used as prevocational work-ability and success-acquisition training technologies.

Methodology—A single subject research design will be employed to assess the utility of 3 EVAT task units. Fifteen deaf-blind or otherwise multiply handicapped blind children between ages of 14 and 22 years will be the subjects in this study located in Jackson, Mississippi.

The project will be conducted in three phases. During the first phase, the EVAT task units will be modified for use by the subject population and a pilot study with the adapted equipment will be undertaken. Training manuals also will be developed. A brief case history of each of the subjects will be collected during this phase as well. The second phase will consist of assessment of each subject's prevocational skills. During the third phase, each subject will be trained in the use of the EVAT task units. On subsequent trials, data will be collected on work proficiency, work rate, work quality, work perseveration level, work repertoire, and work endurance.

Progress to Date—Work has begun to modify the selected EVAT task units.

FY 1985 Activities—The adapted EVAT work task units will be field tested at the Mississippi School for the Blind in Jackson, Mississippi. The reliability and validity of the adapted work task units will be investigated■

Assessment of Eye-Hand Coordination and Manual Dexterity Under Different Illumination Levels and Contrast Conditions

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Research Problem Addressed—This project is an extension of the strategies and techniques developed in RRTC/BLV project R-5, Illumination Level and Color Contrast Studies, to increase knowledge about the effects of visual environment modifications on various types of performance that are basic to many work abilities. Answers to three questions will be sought:

1. To what extent do environmental modifications such as changes in illumination level, contrast, size, and presentation speed affect performance of low vision subjects on tasks involving perceptual and psychomotor skills?
2. How do these environmental characteristics interact to affect performance, and are the effects and interactions consistent across tasks requiring different combinations of skills?
3. How much variation exists among low vision individuals with respect to such effects, and can relationships to subject characteristics be identified?

Methodology—The tasks on which dependent measures are to be obtained tap basic perceptual and psychomotor skill abilities that underlie much visual functioning. This is important because, unlike the familiar job tasks of R-5, these tasks will be novel to the subject and thus require a continuous use of vision. Moreover, the testing for optimal stimulus characteristics will be done on multiple tasks, each requiring a different combination of perceptual and psychomotor skills, allowing for greater generalization of on-the-job skills and an investigation of the consistency of stimulus effects in a variety of tasks.

The number and type of independent variables or stimulus characteristics have been increased, resulting in the following improvements:

1. Contrast will be studied in terms of one of its major components: luminance contrast. The present study will focus on luminance contrast.
2. For each task employed, the two primary independent variables to be manipulated are illumination and luminance contrast. In addition, each will include one or more of the following task characteristics as independent variables: size, speed of presentation, or target speed.

Data collection on each subject can be completed in about two hours instead of the months required in the project on illumination level and color contrast. This allows for better control of motivational variables and the elimination of history effects.

The subjects to be included in this study will be 60 people who are legally blind in the state of Mississippi. To help insure representativeness, subjects will be selected with the cooperation of Mississippi Vocational Rehabilitation for the Blind.

The task-dependent variables of the three tests are: (i) subject's time-on-target record in tracking a paced target path with a stylus; (ii) the number of correctly identified stimuli in a prescribed orientation during a timed task; and, (iii) the subject's ability to accurately identify stimulus patterns and orientations within timed intervals.

Selected Career Development Factors and Outcome of Vocational Rehabilitation Services Provided Middle-Aged and Older Blind Persons

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Research Problem Addressed—This study is an intensive investigation of one of the subpopulations identified in RRTC/BLV project R-4, Functional Outcome for Blind/Severely Visually Impaired Children of State Rehabilitation Agencies. Answers to the following two research questions will be sought:

1. Do middle-aged and older blind clients of rehabilitation agencies differ from younger clients of the agency providing services to them, as well as from one another, with respect to (a) disabilities (primary, secondary, tertiary), (b) proximity to a rehabilitation counselor, (c) services received, (d) funds expended, (e) vocational skill levels, and (f) functional outcome? If yes, to what extent with respect to each?
2. Do functional outcomes of blind middle-aged and older persons closed "26" or "28" by state rehabilitation agencies differ from each other with respect to (a) services provided, (b) client characteristics, and (c) county economic conditions? If so, what factors predict "26" as opposed to "28" closures?

Methodology—A multivariate discriminant analysis will be used to assess functional outcomes and related characteristics of middle-aged and older people from the data base of 619 blind persons whose cases were closed "26" or "28" by state rehabilitation agencies in FY 1978, 1979, and 1980 in Florida, Kansas, Mississippi, and Ohio. Middle-aged subjects will be defined as those persons who were 40 to 54 years old at referral. Older subjects will be defined as those persons who were 55 years old or older at referral. Younger subjects will be defined as those who were 39 years old or younger at referral.

Subjects were selected at intervals according to rehabilitation totals from the four state agency populations in FY 1978, 1979, and 1980. The data base has been built from individual case files abstracted for project R-4. The same statistical analytic procedure will be employed in R-10 as was used in Functional Outcomes for Blind/Severely Visually Impaired Clients of State Rehabilitation Agencies.

FY 1985 Activities—Analysis of data on this project will be completed this year. A technical report of findings will be available from the Rehabilitation Research and Training Center on Blindness and Low Vision■

Predicting the Visual Abilities of Partially Sighted Persons

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The objective of this project is to define a set of measures of visual function that can be used to predict how well partially sighted persons can perform visually guided tasks. The tasks range in complexity from simple discrimination of letters, shapes, and faces to everyday activities. If successful, this project will provide clinicians with new diagnostic tools for assessing visual function in partially sighted persons. The research plan involves:

1. Assessing visual function in a group of partially sighted persons and an age-matched group of normally sighted persons;
2. Measuring performance on visual tasks involving letter discrimination and face discrimination;
3. Quantifying each person's ability to perform everyday tasks, such as travel, shopping, personal hygiene, work, and recreation; and,
4. Determining the relationship between performance of these tasks and measures of visual function.

Visual function will be assessed using both standard optometric techniques and threshold contrast sensitivity. All measures of visual function will be reduced to parametric form for subsequent statistical analyses.

Performance on everyday tasks will be measured with a survey instrument designed specifically for visually impaired persons. The survey instrument already has been validated for this population.

At this stage, we have started gathering data on contrast sensitivity in age-matched normally sighted persons. Our next step will be to gather contrast sensitivity data for a large population of visually impaired veterans■

A Study of the Effectiveness of a Blind Rehabilitation Program

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Purpose—This study assesses the degree of effectiveness of the Blind Rehabilitation Center in bringing about positive changes in the lives of blind patients, and develop means of predicting individual success in rehabilitation training. In order to measure the degree to which the Blind Rehabilitation Center effects changes in patients' life states, the dimensions of life state were defined during a series of pilot studies preparatory to the currently ongoing study. The scales derived from the pilot studies are used to assess the patients' life state prior to rehabilitation and again after treatment. This permits us to measure the amount of change in patients' lives that is due to rehabilitation treatment.

We use a method of scale development that permits an unusual degree of validity and reliability, and so increases precision in specifying the amount of a given skill or characteristic possessed by the individual patient. Our measuring instruments, or scales, can be used in the evaluation of any blind rehabilitation program, and so perhaps aid in improving the quality of treatment and the efficiency of service allocation in all such programs.

Progress—Since the inception of the study, we have developed a general model for the rehabilitation

process in the Blind Rehabilitation Center. We also have developed a set of measures which, taken together, give us a definition of life state. First, there is an attitude toward blindness inventory that measures the attitudes of the patient toward the disability, and of the significant other toward the disability. Second, there is a mood scale that measures the psychological resources of the patients to note the level of anxiety, depression, or other psychological impairment to learning. Finally, there is an activity and mobility inventory that assesses the level of skill in activities of daily living and travel independence. In the course of validating the activities inventory, desire to improve in the activities was measured in already rehabilitated veterans, constituting a measure of unfulfilled needs of these veterans. Each measuring instrument has been validated on a sample of at least 100 patients. In addition, a large number of rating scale analysis programs have been developed for use on computers.

New patients are interviewed before they reach the Blind Rehabilitation Center to assess their life state prior to rehabilitation. When they return home from the Blind Rehabilitation Center they are measured again, and a change score is derived to note the effect the blind rehabilitation program has had on their life state. The measure is repeated 6 months later.

To date, 290 patients have been interviewed prior to rehabilitation; 187 patients have been assessed for changes upon completion of training, and 174 have been remeasured after 6 months at home in order to estimate the degree to which immediate changes are retained. In a progress report prepared for the John Malamazian Blind Rehabilitation Center, it was indicated that positive changes in life state were effected immediately after rehabilitation. Interviewing of patients and processing of already collected data are being continued.

[See also **IV. Spinal Cord Injury, G. Wheelchairs Including Seating and Controls**, Images Project]

2. Mobility Aids

The Effects of Preview Distance on the Mobility of the Blind Pedestrian

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

The optimal distance at which blind pedestrians should receive information regarding their upcoming environment is an important variable for the design of mobility aids. Previous research in this area has not provided a definitive distance or range of distances for the necessary foreknowledge, or preview of the environment.

It is hypothesized that a decline in performance indicates an insufficient amount of preview for the blind pedestrian. Insufficient preview does not allow sufficient time to respond appropriately to upcoming environmental features and also disrupts the pedestrian's processing of other, more global orientation and mobility information, such as route knowledge. Thus, this project assesses a range of these preview distances from 1 to 10 feet to determine at what distances both the overall mobility and a set of specific gait-related parameters of mobility deteriorate.

Preview distance is controlled in the study through the use of a modified Polaroid ultrasonic transceiver which ascertains that an obstacle is at some distance from the pedestrian and causes an audible signal to be produced. Data have been collected and are presently being evaluated.

This study should yield insight into optimal preview distances. Then, future mobility aids can be designed to be more informative and compatible with the user and less disruptive of the basic psychological processes that underlie mobility.

Measuring the Mobility of Blind Travelers

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To perform a valid evaluation of a training program in blind mobility, the means for measuring the effect

of that program on the blind traveler must be available. Previously, two quite different approaches have been taken in assessing the blind person's mobility performance: (i) measuring, either qualitatively or quantitatively, the travel skills of the blind person or, (ii) ascertaining the amount and type of travel in which the blind person is reported to have been engaged. Earlier attempts at measuring both of these have been less than optimal. Moreover, the two types of measures have never been compared in relation to each other. It is now possible to determine the effect of travel skills training on the travel behavior of the trained blind traveler. Recent improvements in both of these types of measures make it feasible to do such a comparison.

This study measures the travel skills and travel behavior of two groups of veterans from the VA Central Blind Rehabilitation Center: a low vision group and a blind group. Each group's travel skills, as measured by the interankle distance measuring system (IAMS), and travel behavior, as measured by the Travel Inventory, will be determined at four times: twice before training, once at the end of the training period, and once 6 months after training. The relationship between travel skills and behavior will be determined for each of these four measurement points. Comparisons between the IAMS and the Nottingham group categories of mobility skills will be made. It is hypothesized that the level of travel behavior at the third and fourth measurement points will not be fully explicable in terms of the level of acquired travel skill. Factors unrelated to travel skills, such as spatial abilities and psychological stress, will result in lower travel activity than would have been anticipated from the level of travel skill. Data are being collected at the present time on this study■

The VA Guide Dog Harness

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Purpose—This is a student design project. The purpose is to design and test new guide dog equipment with more appropriate choice of materials technology. The goal is to develop a harness and leash that have better wear, require less care, have superior esthetics, and have lower production cost.

Progress—Prototypes have been completed for field testing and evaluation. The leather has been replaced by nylon strapping because it is lightweight, more comfortable, requires little care, and is believed to have a longer lifetime. All buckles have been replaced with Scotch-Mate, a product similar to Velcro, because it is infinitely adjustable and perceived to be more comfortable for the dog. The initial harness handles were made from both acrylic and polycarbonate rod. The simplicity, practicality, and esthetics of the new harness and harness handle were rated highly by persons using guide dogs. The new handle excelled as a communication link between the dog and the disabled person. However, preliminary handles have not been as durable as necessary. We are continuing to search for a rod that proves satisfactory to our needs. Possibilites being considered are Lexan, Nylon, and Delrin.

Future Plans—Plans are formulated for the cooperative testing of the VA Guide Dog Harness. Several guide dog schools have expressed a desire to assist in field evaluation. A potential manufacturer has been located and production will follow successful testing■

SONA/SONA-ECS

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Purpose—The SONA/SONA-ECS is a digital radio transmitter-receiver system that has applications for visually impaired persons as an orientation aid and to manually impaired persons as a Decentralization Environmental Control System, ECS.

Progress—Both the SONA and the SONA-ECS have proven to be highly reliable and to function well technically. SONA-ECS has had approximately 4,000 hours of field testing to date, both in a work environment and in a veteran's home. It also is being used to operate a door/wheelchair lift control and interior lights in a van.

Both systems are now being redesigned to simplify the hardware involved by replacing the discrete digital ICs and DIP switches with a single chip microprocessor and a few support devices. This will enhance the system's capabilities, as many modifications and improvements can be implemented through soft-

ware. A broader range of output devices, including input to a computer, can be easily interfaced to the system. The digital coding of the radio signal can also be expanded so that transmitters for different uses or disabilities will send a different generic use code in addition to the device code.

The SONA, Sonic Orientation and Navigational Aid, for the visually impaired traveler is now ready for field testing at the Atlanta Veterans Administration Medical Center. Thirty-five units have been installed and initial testing is beginning to determine some design criteria for improvements in both technical and human factor areas. The use of microprocessor technology in the system will greatly facilitate the implementation of these improvements. One such improvement involves the proposed use of synthetic speech units for those applications where the Musical Language output is inappropriate.

Future Plans—The Atlanta Veterans Administration Medical Center intends to continue development and evaluation of this system in both of its aspects.

This research will center in two main areas: (i) to enhance the performance and capabilities of both systems through the application of microprocessor technology and (ii) to evaluate the SONA as an aid to the visually impaired traveler.

The final result of this research is intended to be the development of products that are low cost and easily manufactured.

The Expansion of a Computerized Information System to Assist Researchers and Practitioners in Developing and Evaluating Theories and Aids to Improve Mobility for Individuals with Low Vision

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Sponsor: National Institute of Handicapped Research

Background—In a previous NIHR grant, a low vision data base was implemented. This data base supported all other grant related research activities, especially in exploring the effects of psychosocial factors on the rehabilitation of low vision persons. A subset of 471 patients were administered a psychosocial inventory. This inventory was developed by the project staff and analyzed by factor analysis, as well as analyzed for suggestive relationships between inventory scores and the demographic, clinical, and functional data items.

Four objective data collection forms reflecting interdisciplinary information needs were prepared for this project. To assure the usefulness of these forms, most local service delivery staff aided in their development. This process of concensus-making resulted in implementation delays and required some retrospective data collection.

Current Progress—Research efforts seek to refine the data base and integrate it with information concerning mobility performance to assist in the development and evaluation of theories and aids.

This existing data base served as the core of the information system developed in this project. All of the original forms were substantially revised, as were the data management and analysis programs. New programs allowing input of information specific to orientation and mobility performance of clients involved with other research projects were written in a way to allow integration with the existing core of over 900 items.

Input manuals containing detailed instructions on the content and coding of the data base items have been prepared. Search and analysis routines have been written and manuals explaining their use in laymen terms are being prepared. These search and analysis routines have been used to provide staff with information needed for presentations, or for finding subpopulations of patients to serve as subjects in specific research projects.

An intelligent report generator has been programmed, which prints English language reports on clients based on information contained in the data base. Data on 420 new patients have been coded at this point, and information on a total of 600 is anticipated to be included in the data base at the end of the grant period.

Another goal of this project is the analysis of the information included in the data base to prioritize data related to adjustment to independent mobility. In addition, a concern in the development of the data base has been for its ultimate use by other rehabilitation facilities. Involvement of clinical staff in the design, attention to pragmatic aspects of implementation of the system, and the design of easy-to-use forms and manuals, we believe, will lead to acceptance of the system, or some subset of the system, by other agencies. Long term goals include using this information as the basis for exploration of knowledge needed for development of computer-based, expert consultation systems.

Orientation and Mobility of Low Vision Pedestrians

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Sponsor: National Institute of Handicapped Research

The project addresses theory development issues in the orientation and mobility of low vision pedestrians through two different research studies. Project 2a, Studies of the Spatial Orientation of Low Vision Pedestrians deals with orientation by examining the knowledge of self-to-object and object-to-object distance and direction relationships within a known environment. Project 2b, Studies of the Low Vision Pedestrian's Visual Environment and Mobility, involves the examination of the effect of travel hazards on the travel ability of people with varying types of vision loss under different levels of illumination.

Project 2a uses data collected from 20 subjects in each of four different groups. The groups are defined by the amount and type of remaining vision (20/70 to 2/200, 20/200 to 20/800, central field loss, and peripheral field loss). Four measurement procedures are used to assess knowledge of a known area. The procedures include straightline triadic distance judgments, functional triadic distance judgments, pointing, and verbal descriptions of routes. The triadic distance judgments require the subject to indicate the longest and shortest relative distances between three different landmarks. The study is designed to investigate differences among the groups across the different types of distance and direction measures through the use of analysis of variance. Multidimensional scaling analyses will be used to portray maps derived from the distance judgments. Finally, multiple regression techniques will be used to intercorrelate different subject variables with the measures of spatial learning and orientation.

Project 2b seeks to identify common hazards to travel, analyze the effects that the types of low vision and illumination levels have on the ability to detect and negotiate the hazards, and identify the visual information used by low vision persons to detect and negotiate the hazards. The hazards will be identified by low vision individuals and orientation and mobility instructors through survey methods. The effects of type of low vision and illumination will be assessed by behavioral measures while the subject is walking a route during which the hazards will be presented. The behavioral measures will include speed of walking and a secondary task procedure. In addition, performance on the behavioral measures will be correlated with tests of visual functioning, including extensive field and acuity measures and tests of contrast sensitivity■

The Effects of Low Vision Aids and Traditional Versus Nontraditional Methods on the Independent Mobility Performance and Stress Levels of Low Vision Individuals

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Sponsor: National Institute of Handicapped Research

Increased levels of stress (as measured by heart rate) have been documented in visually impaired individuals when compared to sighted counterparts in independent mobility situations. In this research project both traditional and nontraditional mobility training procedures are hypothesized to reduce stress levels of low vision pedestrians using low vision optical aids.

Four different treatment groups are compared. Group A receives prescription of low vision optical aid, maximum of 30 hours of orientation and mobility instruction (traditional training procedure) and 10 hours of deep relaxation techniques (nontraditional training procedure) to reduce stress levels and improve mobility performance. Group B receives prescription of low vision aid and 30 hours maximum of orientation and mobility instruction. Group C receives prescription of low vision aid and 10 hours of deep relaxation training. Group D receives prescription of low vision aid only. All four groups receive minimal 1-hour training in the use of the low vision aid. Low vision aids used are handheld telescopes, frame mounted telescopes, or a field enhancement system (30▲ fresnel lenses). Both Single-Subject and Between Group Differences designs are being used to analyze data.

The following information is being collected and analyzed for baseline information, pre-comparison, and post-comparison.

Psychosocial/attitudinal responses:

1. Beliefs About Blindness Scale
2. Type A Personality Test
3. Cognitive-Somatic Anxiety Scale
4. Feinbloom Psychosocial Inventory
5. Spielburger Self-Analysis Questionnaire

6. Low Vision Mobility Attitude Survey
7. Reports from personal journal kept by each subject during participation in the research project.

Mobility:
1. Orientation and Mobility Critical Events
2. Checklist—performed on a predetermined, structured 10 block route that each subject walks—observed by an orientation and mobility specialist.
3. Orientation and Mobility Stress Inventory

Physiological Stress Measure:
Heart rate is recorded by portable heart rate monitor and tape recorder and analyzed on computer for heart rate and variance of heart rate.

It is hypothesized that subjects in group A who receive a combination of orientation and mobility instruction and deep relaxation training will improve mobility skills, reduce physiologically measured stress, reduce self-perceived stress in mobility situations, enhance self image, attain healthier attitudes toward visual impairment, and increase mobility performance. Conversely, the opposite is hypothesized for group D (receiving neither mobility instruction nor relaxation training).

In addition to exploring these hypotheses, another purpose of this project is to explore a multitude of correlations such as: acuity and stress levels; acuity and mobility performance; field of view and stress levels; comparison of varying levels of acuity with mobility function; acuity and attitudes; length of time since onset of vision impairment and attitude toward vision impairment; and, percentage and degree of Type A personalities with vision impairment compared with rest of general population.

Preliminary results are available only for a small number of subjects reported in Single-Subject design. No between group analyses are possible yet.

The project is ongoing until March 1985. Results will be published and available from National Rehabilitation Information Center in Washington, D.C.■

Illumination and Low Vision Mobility

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In the low vision population, the most commonly reported functional problems relate to glare and photophobia. When a person has an impaired visual system, any reduction of visual acuity can have a profound effect on both the perceived and actual ability to travel safely.

This project was designed to explore the effects that sunlenses have on the mobility performance of low vision persons. Subjects are randomly placed in either a control or treatment group. Each group is required to walk a 10 block route in a residential and small business environment. The treatment group wears sunglasses; the control group does not.

Data are collected on heart rate (through a heart monitor connected to a tape recorder), illumination levels, visual acuity with and without the sunglasses, mobility performance, and environmental characteristics such as crowd density, temperature, and traffic density. It is hypothesized that group differences will be present on these measures, with the treatment group having a lower heart rate, better visual acuity with sunglasses, and better mobility performance. Basic descriptive statistics, t-tests, and exploratory data analyses will be used to test the hypotheses■

Superfold Cane Development Program

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Cane Design I—Our first design consisted of placing a compression spring in each section of the cane, thus permitting sections to be replaced by removing a retaining screw from individual sections. The compression spring replaced the elastic cord, eliminating the failure mode of the elastic cord breakage. Also, the compression spring could not be overstressed, thus extending the life of the cane.

However, it was determined that the cost of the cane would be approximately twice that of existing

canes; the weight would be increased and balance point shifted toward the tip; and, the spring inside the cane section made noise when it touched the aluminum tubing sections. For these reasons, Cane Design I was rejected.

Cane Design II—Our second attempt to remove the elastic cord failure mode was the use of a constant force spring contained in the handle. Attached to the spring was a plastic non-elastic cord which had excellent wear characteristics and over 1,000 pounds of strength. The cord material was of special fibers manufactured by Dupont plastic and coated with a Teflon surface with excellent wear characteristics.

A number of these canes were produced for evaluation by the Jewish Guild for the Blind. Their evaluation was negative primarily for one reason. In order to take the cane apart, it was necessary to separate the cane from the tip end since the spring was in the handle. This design then also was rejected.

Cane Design III:

1. **Elastic Cord**—The previous approaches seemed to indicate that even with the failure mode associated with the elastic cord, this was still the best method of holding the cane together. In some of the existing canes the handles had to be removed to replace the elastic cord, and with age, the handle tended to adhere to the aluminum tubing, making it difficult to remove. We solved this problem by placing the elastic external to the handle on the upper end, and external to the tubing on the lower end. The cord was held in place by simply tying a knot in the upper and lower ends. Thus the handle would not have to be removed, and the tension on the cord could be changed by simply tying the knot at the tip end at a different location.

In order to increase the strength and reduce the weight of the cane, we contacted Alcoa to find materials which were substantially stronger than those used in existing canes. The tubing was primarily of the type utilized in aircraft in strong aluminum alloys developed for the aircraft industry. Of the two recommended types, we selected one which had over twice the tensile strength of ordinary cane tubing. The cost was approximately 50 percent less than the price of the strongest material available but was still over twice the cost of conventional tubing.

2. **Cane Joint**—Many existing canes are built with a tapered joint. Because the joint is aluminum against aluminum, there is excessive wear and a tendency to stick. Tapered joints also tend to freeze, making it difficult to remove cane sections. The integrity of the joint was also related to the tension of the elastic cord; positive pressure was required to maintain it, and this further increased the difficulty in removing sections of the cane.

A prime consideration therefore was to reinforce the joint. We first designed an insert made of plastic. Nylon, which is used in gears and has superior wear characteristics, was our first material. The entire joint was made of nylon. Tests performed in AFB Labs indicated that (i) the nylon was not strong enough and caused the cane to break at the joint, and (ii) nylon absorbs moisture and expands, which caused the joint to become tight when exposed to high humidity.

To solve these problems, we changed the plastic material to Delrin, which does not absorb moisture, and placed a stainless steel insert within the Delrin. This stainless steel was stronger than the aluminum material and tests on the cane showed that the joint would not fail—the aluminum tubing would fail before the joint. Since the major reason for failure of canes was the joint, this should result in better cane performance and increase the life of the cane.

The cane joint was made with a straight entry point instead of a taper. In order to make the insertion easier, the section near the tip of the joint was made smaller at the tip and larger at the base, enlarging the overall size of the insert slightly. The aluminum tubing was larger at the entry point, and smaller (approximately 1″) inside the material. This permitted the joint to be assembled to within the last eighth of an inch in a free condition requiring no pressure, with the joint being held tightly during the last eighth of an inch of motion. Since there was no taper, the joint did not tend to vibrate loose with use, thus creating less tension on the elastic cord.

The completed Cane Design III has an elastic cord down the center, a nylon tip fabricated of stainless steel inserts around Delrin plastic, and high strength aluminum tubing.

Evaluation—Tests performed by the Carleton Laboratory at Columbia University in September 1983 showed no significant change in the canes after 10,000 insertions. In addition, the cane strength was superior when compared with other canes. The new cane was tested for over one year and 1,000 canes were produced. A close watch was made on their performance. We found that tips were too loose on some canes and a fracture occurred in the aluminum. This problem was due to quality control in manufacture, related to oversized inserts and tips.

We had recommended tightening the joint in the last eighth of an inch in each section, by tapping the cane on the ground, forcing the joints together and making the cane rigid. The completed cane would then feel like a single aluminum section with no perceptible wobble in the joints. Occasionally, however, the joint would not go into the aluminum tubing and when the cane was tapped to tighten the joint, the hard stainless tubing would cut or nick the aluminum, which would eventually score the plastic insert and reduce cane life. This was a design flaw which had not shown up in our initial field tests.

This problem was solved by placing a plastic insert around the end of the stainless, beveled at a 45 degree angle, with a hole to center the elastic cord. The insert guided the sections together, reducing noise since the elastic was centered, and reducing the possibility of the cord touching the aluminum. This eliminated the failure mode since the stainless steel could not touch the aluminum even if the joint was not centered.

This change was made in the last 600 canes sold. Fifty canes were delivered to the Veterans Administration for evaluation in April 1984.

3. Reading Aids

Development of a Graphic Braille Display

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Problem—Computers are rapidly becoming prerequisites for educational and vocational opportunities. There are numerous public and private groups actively seeking means of making computers accessible to the visually impaired. The most common means of access are synthetic voice outputs, single-line refreshable braille displays, and large print displays. None of these provide access to graphic information (e.g., bar graphs, pie charts, histograms, etc.). Thus, there is a pressing need to make such graphic information accessible to the visually impaired.

A means of presenting such information would have numerous other applications (for example, in presenting trigonometric and geometric mathematics, geographic maps, flow charts, organizational charts and diagrams of instruments, buildings, and equipment). These applications are relevant to all visually impaired individuals regardless of age or occupation.

Significance—The four blind rehabilitation centers of the Veterans Administration routinely provide training on a variety of computer-related devices. Most of this training is directly related to the veteran's vocational or educational objectives. Current training is often restricted to programming or word processing tasks because of the lack of a suitable means of presenting graphic and/or tabular materials. The development of a tactile graphic display would significantly improve the ability of these centers to provide comprehensive training in the use of adapted computer aids.

The development of such a display would also be directly applicable to many non-veterans who have severe visual impairments. Current estimates indicate that over 60,000 veterans and over 1.5 million non-veterans are blind.

Background—Since 1981 the Western Blind Rehabilitation Center (VAMC, Palo Alto) has been providing training in the use of adapted computer aids. More recently the center has entered into a cooperative program with the Sensory Aids Foundation of Palo Alto to offer an expanded training program to visually impaired veterans and non-veterans and to rehabilitation professionals who need such knowledge to work effectively with their own clients. The center also has some 7 years experience in research and evaluation of computer aids for the visually impaired. Much of this work has been a cooperative endeavor between the Western Blind Rehabilitation Center and the Rehabilitation Research and Development Center.

The American Foundation for the Blind has recently designed a graphic braille display which is thought to be suitable for providing graphic and alphanumeric information. The current project will allow continued development of that display, the development of needed software, and evaluations of the display in both laboratory and field-testing conditions.

Approach—The research will combine hardware and software development with concurrent evaluation so that the design process can immediately benefit from information obtained in the evaluation process. It will be facilitated by the initial construction of three

prototype displays. This will allow two displays to be used for field and laboratory testing and one prototype to be used for hardware refinement. The three units can be rotated (from the American Foundation for the Blind to the Western Blind Rehabilitation Center) so that advances in hardware are immediately incorporated into the evaluation without the loss of time typically encountered when prototypes malfunction or are returned for modification. Software development will focus on Apple II + and IIe computers and on CP/M-based systems. These encompass the most widely used computers.

Status—The project received merit review approval in December 1983 and is currently awaiting the availability of funds (anticipated in October 1984.)■

The Positive Braille Writer

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Sponsor: Royal Commonwealth Society for the Blind

Blind people read and write by using braille, which represents letters through the presentation of various combinations of raised dots.

For the first 100 years after its invention, braille was produced manually by placing paper on a frame and pressing down through the paper with a stylus. This meant that to produce correct characters reading from left to right, the stylus had to be used to impress the characters in reverse from right to left. Thus blind children and newly blinded adults had their difficulties compounded by having to learn to write backwards as well as learning to read.

The great interest in blindness which came about as a result of Second World War casualties led to the invention of a mechanical braille writer that created characters in the correct form from left to right. This meant that the reading and writing process was simplified with the added bonus that the operator could read what had just been written, rather than having to turn the paper over, because the pins that produced the dots embossed upwards from the rear of the paper.

Mechanical braille writers cost in the region of $350, and although they are widely used in the industrialized countries, they are prohibitively expensive for developing countries. Perhaps 5 percent of blind children in developing countries have access to any kind of formal education and one of the major factors retarding the growth of the education for blind children has been the cost of equipment. Until recently the choice was between a very difficult and primitive form of braille writing and a very expensive machine.

This problem has now been solved through Dr. Rudi Sampimon's simple invention. He took a totally fresh look at the problem of braille and instead of the pointed stylus making an impression on the paper, which had to be reversed for reading purposes, he produced a hollow stylus matching a raised pin in the writing frame. When this hollow stylus is employed, on paper over the raised pin, braille can be produced from left to right in the same way that it is produced by mechanical braille writers, but at no greater expense than the traditional stylus and frame. Dr. Sampimon's invention means that, for the first time, first-rate equipment for writing braille and doing simple calculations will be available at a very low cost—and this has tremendous implications for the future of the education of blind children in developing countries.

The Royal Commonwealth Society for the Blind welcomes this invention with enthusiasm, and hopes that it will soon be possible to mass-produce the new form of positive braille writing equipment for particular use in developing countries■

A Large Print Word Processor for the Visually Impaired Person

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Purpose—The Large Print Word Processor is a generic equivalent of cassette-braille machines for large print users. The system features a large print display and typewriter keyboard with microcassette storage of information.

Progress—Construction of prototype test units is still proceeding. There are currently two units in working order. This system is based upon the Typecorder, a battery powered portable Sony word processor. The Typecorder has been modified to accept an intelligent interface and a large print display suitable for use by visually impaired persons. The new system is designed as an electronic add-on and is plug compatible with the Sony LCD display. The Typecorder interfaces with a new display, the Deca 245A. It is a vacuum tube

fluorescent display with a standard ASCII character display set. To connect the Typecorder with the Deca display, an interface circuit had to be built. This interface allowed the Typecorder to handshake with the Deca display; it had to transform the Typecorder's cursor instructions into instructions recognized by the Deca display. These two functions are handled by the Intel 8741 peripheral controller. A third function of the interface is to provide electrical isolation between the CMOS circuitry of the Typecorder and the TTL circuitry of the Deca. This electrical buffering is handled by Motorola MC14503 buffers.

The completed prototypes now offer an alternative display with 40 characters of 0.2 inch height. The display is of high resolution and considerable brightness. Preliminary tests indicate it to be of great value to the population that needs it at a reasonable cost, especially when compared to the alternatives. The problems remaining include the provision of reading material on the Sony microcassette format and the legal repercussion of such an attempt.

Future Plans—Work will continue in locating a suitable manufacturer for this product. Initial contacts have been made with potentially interested manufacturers, and the research team is working closely with these to evolve a production-ready prototype■

Musical Language and Large Print Considerations in Human Factors Engineering

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Purpose—To determine the optimal, most cost-effective methods of interfacing the visually impaired person to computer display/digital information recovery and entry systems.

Progress—A preliminary study has been conducted that consisted of analytical interviews with a visually impaired computer user. The recommendations which resulted from these interviews were published in a paper entitled Human Factors Considerations in the Development of a Large Print Display for the Visually Impaired Computer User, published in the proceedings of the Second Annual Conference on Rehabilitation Engineering, June 1984, Ottawa, Canada. In addition, some recommendations of the interviews have been implemented on an Apple computer and are being tested by several visually impaired computer users. It also was suggested that the musical language be combined with the large print displays as a means of providing bimodal display recognition. This is now being implemented and will soon be tested by several visually impaired users. The musical language referred to here was the result of a graduate feasibility study, the results of which have been discussed in previous reports.

Future Plans—Future plans are to continue the implementation of the recommendations of the above-mentioned study and further testing of these implementations by computer users under a variety of work and home situations. Finally, the results of these implementations and tests will be used as guidelines in the development of a Video Emulator Monitor and Display for the visually impaired computer/word processor user. VMED is a universal device that will act as an interface between any computer and the visually impaired person■

Development of a Hand-Guided Reading Aid for the Visually Impaired

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Need—For both professional and personal reasons, visually disabled people often need direct access to inkprint—that is, without requiring the intervention of a sighted person either as a reader or braille translator. Devices such as the Optacon and the stereotoner, which attempt to meet these needs by converting letter shapes into identifiable tonal patterns or into non-braille tactile displays, require, in practice, considerable skills and training on the part of the user. Speech-output readers (e.g., the Kurzweil Reading Machine) can serve a large population, but current models are both expensive and non-portable. The need, therefore, is for a convenient, affordable, and portable reading aid.

Background—In the mid-70's, Telesensory Systems, Inc. undertook to make a hand-guided, speech-output reading device by attaching an optical character recognition module to their existing Optacon camera. Seven of these talking Optacons, officially designated

the Hand Scan 1, were distributed to various centers for evaluation. The resultant conclusions suggested that while the time was ripe for a device of this sort, and while the Hand Scan 1 provides a clear proof of concept, the existing units were too costly, bulky, and operationally demanding. This VA-funded work stems from a proposal to develop a device removing the Hand Scan 1 shortcomings found during evaluation.

Approach—A hand-guided reading aid is being designed, and three prototypes are to be constructed. The devices have been designed to be versatile, portable, less expensive than functionally comparable devices, and easy to use. This reading aid will capture inkprint images via a small, hand-guided camera capable of reading printed materials over a wide range of type sizes and styles. The device will use adaptive signal processing techniques to select appropriate thresholds and magnification levels during operation, and additionally will provide the user with feedback to assist in the task of line tracking while allowing tolerance for error in hand tracking.

The design will replace complicated mechanics and optics with signal processing techniques. To make the aid versatile in use, it has been designed to interface to a variety of output devices, including speech synthesizers, low-vision magnified letter displays, Optacons, stereotoners, and commercial personal computers. These options should allow users to configure personalized systems in accordance with their own needs, abilities, preferences, and pocketbooks.

Status—Hardware items for all major components in the project development stage have been acquired, including input optics, sensor CCD and RAM chips, central microprocessors on their printed circuit boards with memory chips, card cages with power supplies, printed circuit boards to serve input and output interfacing, an Optacon with light box, a stereotoner, various quality speech synthesizers, and a compiler and cross compiler to allow software development to proceed in a high-level language on the center's VAX computer. These components are currently configured into an operational development system, enabling software generation and testing to proceed for the final device. A laboratory system for capturing images using an Optic RAM behind camera optics has been developed and is being debugged. It is planned that in the reading aid prototype, the Optic RAM will receive images which have been reduced in size by a demagnifying fiber optic element and focused on the proper plane by a Selfoc self-focusing fiber optic unit.

Software development is being carried out by project personnel, with the collaboration of students and EE professors from Stanford and Cornell Universities. Packages to effect auto-correlations, adaptive thresholding, character separation, and preliminary optical character recognition are under development. Output interface work is at an advanced stage. The interface board to the Optacon has been completed and interfaced to the 68000 microprocessor, allowing that output device to run under our device's microprocessor control. A stereotoner that attaches to the Optacon is operational as well.

Work in progress focuses on completing the design and building a prototype image input device, developing the software to incorporate into the image preprocessor (to handle adaptively thresholding, magnification, textual line finding, and character finding), and the optical character recognition module■

Reading Aids for the Blind

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Sponsor: Institute for Bioengineering
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The first project was the development of a novel system for the production of high quality embossed maps. One part of the evaluation concentrated on the problems of distinguishing different embossed symbols; this involved over 50,000 tests and 250 blind people. The other part of the evaluation was informally testing maps of the insides of buildings, shopping centers, and neighborhoods.

A computer-based system was developed for the production of a wide range of short documents in contracted braille. The system was evaluated by transcribing two million words of text into contracted braille. This system has been adopted by the Royal National Institute for the Blind. A further development was a microprocessor-based transcription system for the local production of braille. The Braille and Inkprint Text-processing System (BITS) is used by National Deaf-Blind Helpers' League, Lloyds Bank, and Warwickshire Association for the Blind.

The Braille and Speech Information System (BASIS) permits a blind person to write in contracted braille and obtain high quality print copies. The system incorporates word-processing facilities and also permits a sighted typist to input text for translation to

contracted braille, which is then recorded on a paperless braille device.

Deaf-blind people are severely restricted in their access to information such as the news and weather forecast. A system has been developed to permit information from the British Telecom Prestel viewdata system to be automatically produced in braille.

Lack of privacy is one of the most serious deprivations caused by blindness, therefore the availability of bank statements in braille can be important to some blind individuals. In order to be useful, bank statements must be current and errors can not be tolerated. These conditions are met by the automatic transcription of statements from digital data provided by the banks. Lloyds and Midland banks use this system on a regular basis.

For a blind person working in a scientific or technical area, keeping up to date with his subject raises special problems. A pilot scheme involved obtaining computer tapes of abstracts from INSPEC and Psychological Abstracts each month. The blind users specified their interests in terms of the indexing system used by the abstracting service. A computer program automatically selected the abstracts of specific interest to each blind person, translated them into contracted braille and output on an on-line embosser.

In the printing industry, compositors' tapes have been in use for many years. Error-free computer-compatible tapes are now available with the introduction of computer-based composing systems. The project involved an examination of the codes used by printers and development of programs to convert these tapes to the format required by the braille translation program.

The first series of experiments involved a compensatory tracking task with random input signals with five one-dimensional displays. The analysis of results included a comparison of the measured closed-loop frequency response with that obtained from a modified form of cross-over model. From these results it was possible to define two performance parameters for assessing display. The second series of experiments involved a comparison between audio error displays and a visual displays in terms of monitoring the change in operator's response to a step change in the frequency bandwidth of the input signal■

B. Deafness and Hearing Impairment

Development of a Cochlear Prosthesis for the Profoundly Deaf

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Sponsor: National Institutes of Health
(National Institute of Neurological and Communicative Disorders and Stroke)

This progress report combines results on three NIH contracts and one NIH grant, all directed at various facets of the development of a cochlear prosthesis for the profoundly deaf. The facets on which we report are, (i) development of cochlear stimulation arrays, (ii) development of transdermal electronics for stimulating the array, and (iii) developing speech processing strategies for proper electrical encoding of speech to yield speech discrimination in human subjects.

The work on electrode array development has focused on using thin film structures and photolithographic techniques to achieve electrically and mechanically stable stimulation arrays. Electrode arrays may be either of a rigid variety intended for insertion in the auditory nerve as it exits in the cochlea or a flexible variety to be inserted in the curved scala tympani chamber of the cochlear. For both types of electrodes, achieving arrays that preserve insulation integrity and adhesion between layers under protracted years of immersion in a biological environment is the principal difficulty. For the rigid electrode array we feel we have solved most of the problems using a sapphire substrate, tantalum conductors, and a multilayer thin film insulation of which Ta_20_5 and Si_3N_4 are important members. For the flexible array we are working with a polyimide-platinum-polyimide sandwich for which we have solved many problems, but with which we still have significant adhesion problems; the stimulation pads tend to come loose from the polyimide substrate when soaked in saline and stimulated.

For driving the implanted array, we have developed several generations of implantable receiver-stimulators. For all these, both power and instruction are transmitted to a fully implantable device. We now have on test an eight-channel receiver-stimulator that uses an rf link to deliver power and a digital ultrasonic link to deliver data. The unit features all-custom integrated circuit chips, and is hermatically sealed in a cylindrical titanium package roughly the size of a

quarter. Our psychoacoustic tests with volunteer implant subjects have demonstrated that successful speech processing strategies probably require greater timing flexibility and current waveform control than this unit affords. We also find that the ultrasonic data link is the most failure-prone component of our system. We have developed to the breadboard stage a more advanced eight-channel system with both data and power carried over the rf link, and with greater timing and wave shape capabilities. This unit has not yet been packaged, but is being subject to bench tests.

Perhaps the most difficult of all the tasks facing development of a truly effective cochlear prosthesis is that of identifying and implementing a speech processing strategy that encodes speech into a pattern of electrical stimulation which the brain will interpret successfully as speech. Defining the appropriate speech processing strategy involves psychoacoustic and psychophysical tests with human volunteers to characterize the percepts elicited by electrical stimulation and the speech discrimination achieved by various candidate speech processing strategies. In the last year, such studies have been conducted intensively on two eight-channel implants and in a less intensive fashion on three single-channel human implants. We have established that we are able to achieve significant speech discrimination using multichannel stimulation on the multielectrode subjects; whereas for single-channel stimulation of the same subjects, we can improve their auditory communication skills somewhat, but not achieve significant speech discrimination. Portable speech processors embodying the most successful multichannel speech processing strategies are being designed. It is interesting to note that the speech processing strategies most successful for the two subjects are quite different■

Design and Evaluation of a Wearable Vibrotactile Aid for the Deaf

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Sponsor: National Institute of Handicapped Research

The purpose of this project is to develop a wearable tactile aid to represent the voice pitch (fundamental frequency) of speech sounds received by the aid. Such a pitch-indicating aid is intended for use primarily as an aid to lipreading, and also may be used for distinguishing environmental sounds that have distinctive fundamental frequencies.

The sound-spectrum above the fundamental, which distinguishes among the speech and environmental sounds, will not be represented. It has been well demonstrated that adding only the pitch sound to lipreading affords a large improvement. Thus, we believe that a tactile pitch aid has considerable potential. The project has designed methods of pitch extraction that are realizable with wearable microprocessor chips, has selected vibratory transducers that have suitable band width and power characteristics, and is now building a prototype of the aid■

Development of a Digital Hearing Aid and Fitting Procedure

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

The objective of this research is to develop a new hearing aid concept, and a companion computer-based hearing assessment and fitting procedure. The hearing aid uses digital signal processing methods

that allow auditory signal processing to be flexibly adjusted to fit the patient's hearing deficiency. The computer-based audiometer system controls the measurement of the patient's residual hearing, and uses the data to specify the hearing aid characteristics.

The digital hearing aid that is worn home by the patient at the completion of the clinical visit is, in effect, an integral part of the hearing evaluation and, therefore, the individual acoustic variability introduced by the size of the patient's ear, the ear hook, the connective tubing, and the ear insert are correctly accounted for in the fitting procedure. Since the hearing evaluation and fitting procedure is automated, the clinical visit is simplified and shortened with concomitant benefit to the patient and audiologist.

Project Goals—Specific tasks are: (i) to construct a breadboard simulator of the digital hearing aid from conventional components that operates in real time, (ii) to study the performance of the breadboard connected to an ear-level, hearing aid mockup containing the microphones and receivers, (iii) to develop a computer-based clinical test system and programs for controlling the aid during testing and for controlling the test protocol, (iv) to study the perception of noise, distortion, and annoying sounds with hearing-impaired listeners as related to the hearing aid, (v) to fabricate a small number of pocket-sized versions of the digital hearing aid, and (vi) to evaluate the pocket-sized versions under natural conditions of signal and noise in field tests.

Work related to the first three goals will be completed this first year and is described below.

The Digital Hearing Aid Simulator operates in real time and has been designed with the capacity for testing a wide range of signal parameters. The simulator is connected to an ear-level mockup containing the microphones and receivers of the aid. The simulator consists of six high-performance digital signal processors (DSP). These are low-cost integrated circuit chips manufactured by Texas Instruments. One DSP controls the system bus, the analog-to-digital converter subsystem, and the serial interface to the host computer. Four DSPs provide the multiband filtering and limiting of the signals; their output values are routed to the sixth processor, which sums and interpolates the samples and passes them directly to the digital to analog converter.

The computer-based clinical test system has been assembled, and the programs for this system are under development. One program will act like an automatic audiometer and will measure the patient's auditory area (threshold, MCL, and UCL) and adjust the characteristics of the hearing aid according to a specific fitting rule. Another program will administer speech intelligibility tests under simulated conditions of speech, and noise for the purpose of testing the digital hearing aid.

Acoustic Feedback Suppression in Hearing Aids

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Background—Acoustic feedback is a problem to all hearing aid users and to all audiologists who fit hearing aids. In fact, it is one of the major limitations of fitting high-gain aids to those with severe hearing loss.

Hypothesis—The purpose of this project is to answer the following long-standing questions which have plagued engineers and audiologists:

1. What are the physical mechanisms that facilitate the squeal of acoustic feedback and which, if any, of these could be altered in predetermined ways to suppress feedback?
2. How does the presence of the feedback path from vent outlet back to the microphone affect the shape of the frequency response of an aid that is not undergoing feedback?
3. How effective are recently developed earmold designs for suppressing acoustic feedback?
4. Could any of the current schemes for suppressing acoustic feedback in public address systems be adapted to hearing aids?
5. Could a microprocessor-based, adaptive system be utilized in a feedback suppression scheme designed specifically for hearing aids?
6. Could a feedback-suppression circuit, microprocessor-based or otherwise, be designed to meet requirements such as size, maximum allowable current drain, etc. of a head-worn hearing aid?

Methodology and Preliminary Findings—A hearing aid's stability (i.e., a measure of the likelihood that it will squeal under a given set of conditions) may be judged by determining values of its open-loop transfer function GH. In particular, stability determinations are made by comparing values of GH with those known to cause feedback in other systems. Conse-

quently, preliminary work on this project has concentrated on methods for (i) determining GH of an in situ hearing aid and (ii) avoiding those values of GH that are known to cause feedback.

A mathematical replica of this portion of the GH transfer function lying between the vent outlet and the microphone has been developed. This replica is currently being incorporated into a mathematical model of an entire in situ hearing aid. Preliminary work indicates that the one-port rendition of this model is inadequate to explain signal flow in an in situ hearing aid. Investigators have replaced this with a more realistic two-port rendition.

Investigators also have designed and built two different microprocessor-based, adaptive feedback suppression systems. In both systems, low-level pseudo-random noise (PRN) is injected into the circuit just ahead of the amplifier. That portion of the original PRN that returns to the microphone via the feedback path is monitored at the microphone output. A microprocessor then utilizes these two signals—the original PRN and that returning via the vent—to compute the open-loop transfer function GH of the hearing aid. In one system, called the time delay/notch filter (TDNF) system, the microprocessor uses computed values of GH to automatically place high-Q notch filters at those frequencies where feedback is most likely to occur.

In the other system, called the active feedback cancellation (AFC) system, the microprocessor uses computed values of GH to create an estimator. The estimator causes the input informational signal (e.g., that containing information such as speech and not PRN) to react destructively with signals returning via the vent outlet, thereby canceling the effect of the feedback path.

Preliminary results indicate that 6 to 8 dB of additional stable gain can be achieved with either of these systems.

Investigation of Acoustic Reflex in Elderly Persons

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The report period covers termination of one project (above) and initiation of another.

A large-scale laboratory study was completed on the morphology of the acoustic reflex response. The acoustic reflex, activated with tones and noise, was measured with an aural acoustic immittance instrument. The investigation utilized a new digital instrument, coupled with a quantitative approach to analysis and reduction of acoustic reflex data. Reduced data contained predictably large intersubject variance, but the analytical procedure was sensitive to small, intrasubject changes. Results revealed age-depended trends in several measures related to amplitude of the acoustic reflex response. The relative success of the quantitative approach has implications for assessment of acoustic reflex in persons with hearing loss. The data have been presented at a recent professional meeting and are being prepared for publication.

The new project is entitled Implementation of Digital Measurement of Aural Acoustic Immitance. The project involves continuing development, implementation, and evaluation of a digital acoustic-immittance instrument for improved quantitative measurement of aural acoustic immittance. The instrument is a computer peripheral with measurement capacities far exceeding those of existing acoustic-immittance instruments. The new system will allow efficient acquisition of large amounts of data in single test sessions, supporting rigorous clinical evaluations, alteration and tailoring of diagnostic routines, rapid assessment of new clinical measures, and exacting research applications. The system will be evaluated on a clinical population.

Work completed on the new project during the first few months includes modifications of the digital instrument's sample rate, pressure range, and monitor software. In addition, support software has been written for data reduction/measurement and for statistical analysis, and a paper on digital measurement of aural acoustic immittance has been prepared for publication.

A Psychophysical Model to Characterize Sensorineural Hearing Loss

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The purpose of this research program is to characterize the suprathreshold auditory function of an individual with sensorineural hearing loss (SNHL) by means of a theoretical model of pitch processing

(developed in our laboratory), and then to use that characterization to design a signal processing system to compensate for the hearing loss. If the results of the current research indicate that the model is useful in designing compensation systems — hearing aids — for SNHL subjects, the next major phase of the research will be the adaptation of these methods to the clinical setting.

The model was developed originally to explain aspects of pitch perception in subjects with normal hearing and then was shown to account for the results of a series of experiments on pitch perception in such subjects. Two factors suggest that the model may be useful in precisely defining the deficit in SNHL: (i) the close correspondence between the stages of the model and the functional parts of the peripheral auditory system thought to be damaged in SNHL, and (ii) our development of psychophysical methods to measure the parameters of these critical stages of the model in normal-hearing human subjects. If the model accurately represents peripheral auditory function, then the model with parameters measured on a subject with SNHL becomes a model of the hearing loss that can be used to define the properties of a hearing aid fitted precisely to that loss. The hearing aid should be such that for any sound input, the hearing aid plus the hearing-loss model produces the same output as the (unaided) normal-hearing model. To the extent that an individual's hearing-loss model corresponds to that individual's hearing loss, it thus defines the ideal hearing aid for that individual.

The hearing aid defined by the model (as described above) for each particular hearing-loss subject will be tested using speech stimuli modified to simulate the action of the aid by means of digital signal processing software. These simulated hearing aid outputs will then be generated with a digital-to-analog conversion system and presented to the subject through standard hearing aid receivers. The speech recognition performance of the SNHL subject with their aided stimuli then can be compared with these subjects' performance on unaided stimuli and with the performance of normal-hearing (control) subjects with unaided stimuli presented under exactly the same conditions.

At this time we have completed a series of psychophysical experiments, including those experiments needed to define the parameters of a hearing-loss model, on over 20 SNHL subjects. The results of these experiments support the following conclusion:

1. All of our subjects have sufficient frequency resolution remaining in one or both ears to receive the frequency information critical in understanding speech.

2. The model parameters can be defined for such subjects throughout the necessary range of frequency and intensity.

3. The parameters thus defined are consistent with our current understanding of the nature of sensorineural hearing loss.

4. Binaural diplacusis is present in some SNHL subjects and a correction for binaural diplacusis may have to be incorporated into the hearing aid for binaural testing and use.

Current work includes the preparation of the digitally processed (aided) stimuli as well as the continued basic psychophysical testing of additional SNHL subjects. In the coming year, we will perform the first critical tests of the new hearing aid using the digitally processed speech stimuli■

An Electrotactile Aid for Treating Sensorineural Hearing Loss and Aphasia

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During the past 3 years we have conducted an investigation designed to test the efficacy of tactile representation of auditory stimuli for improving speech discrimination in patients with severe sensorineural hearing loss and auditory comprehension in patients suffering aphasia.

Study patients wore a tactile belt on the abdomen that converted frequency, intensity, and temporal auditory information into tactile patterns that can be perceived on the skin. Stimuli were environmental sounds and words generated by a computer analog system. These were presented in three modes — auditory, tactile, and auditory-tactile combined — in a modified random assignment of treatments design. Baseline, pretreatment, and performance were determined and followed by 20 treatment sessions and a withdrawal phase post-treatment. Hearing and language criterion measures were administered pretreatment and post-treatment.

Our results were mixed. Mean performance for a group of normal subjects was 28 percent correct in identifying environmental sounds and 61 percent in identifying words in the tactile mode after 10 hours of training. Sensorineural patient performance on environmental sound identification, after 20 1-hour train-

ing sessions, showed a mean improvement of 10 percent in the auditory mode, 17 percent in the tactile mode, and 15 percent in the auditory-tactile combined mode. On the word identification task, sensorineural patients displayed a mean improvement, following 20 treatment sessions, of 7 percent in the auditory mode, 17 percent in the tactile mode, and 15 percent in the auditory-tactile combined mode. Aphasic patients, in the environmental sound task, displayed a mean improvement post-treatment of 8 percent in the auditory mode, 14 percent in the tactile mode, and 7 percent in the auditory tactile combined mode. On the word recognition task, post-treatment mean improvement in the aphasic group was 5 percent in the auditory mode, 0 percent in the tactile mode, and 3 percent in the auditory-tactile combined mode. Variability in improvement among patients in both groups was rampant.

Comparison of pre-treatment and post-treatment performance on the general hearing and language measures displayed similar variability among patients in both groups. On the Minimal Auditory Capabilities Battery, sensorineural patients showed a mean pre-treatment to post-treatment improvement on seven subtests with a range of five to nine subtests. On the Porch Index of Communicative Ability, aphasic patients showed a mean pre-treatment to post-treatment improvement of six percentile units with a range of zero to nine percentile units.

Our results indicate some promise, certainly not proof, that tactile representation of auditory stimuli may improve auditory discrimination in some sensorineural patients and auditory comprehension in some aphasic patients. Variability in performance among patients suggests tactile instruments may not be ready for tests in clinical treatment trials. More basic explorations on the psychophysical aspects of tactile representation of auditory stimuli and comparisons among the available tactile aids should precede clinical tests of the efficacy of these instruments to assist those with impaired auditory systems■

Changes in Frequency Organization of the Cochlea During Aging

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Research Hypothesis—We recently showed a development change in the frequency organization of the cochlea. Our data indicated that the site of maximum stimulation of the basilar membrane shifts toward the apex during development. The purpose of the proposed studies is twofold: (i) to determine the functional correlates of this basal to apical shift during early development, and (ii) to determine if similar changes in frequency organization occur in the aged cochlea. We propose to use the avian auditory system as a model system to demonstrate these changes in frequency organization. Our past experiments have shown the utility of this model system for studying auditory ontogeny; the proposed experiments would extend this utility into aging and senescence.

Development changes in basilar membrane size, mass and/or stiffness could cause the shifts in frequency organization we have seen. Such changes in basilar membrane dimensions and elasticity have been reported in the aged cochlea. Therefore, our major hypothesis is that in old age, as in early development, changes in frequency organization are occurring.

Methodology—The first group of experiments are designed to investigate further the functional correlates of a changing place code for frequency during ontogeny. We will accomplish this by examining eighth nerve compound action potential (AP) threshold after acoustic overstimulation in chicks exposed to an intense pure tone stimulation at various ages. Preliminary results in a similar experiment indicated that the frequency of maximum threshold shift was higher in older animals even though the stimulation frequency was the same (and the location of hair cell loss was the same) as in younger animals at the same age. Confounding these results were the facts that anatomical results were taken from separate animals and survival time after stimulation was longer for older animals. The proposed experiment is designed to eliminate these confounding variables.

The second group of experiments deals with aging and auditory processing in the Japanese Quail. After the normal effects (anatomic and functional) of aging have been determined, we will proceed to study possible frequency organization changes as a function of aging. Pure tone acoustic overstimulation has been used to define frequency organization of mammalian cochlea. We have shown previously that it can be used with similar specificity for frequency organization of avians. In the proposed experiments, pure tone acoustic overstimulation is used to create discrete, localized regions of sensory cell loss and AP threshold shift. The localization of sensory cell loss is used to define frequency organization in the cochlea

during aging. AP thresholds are measured to determine corresponding functional changes during aging.

Goals—The proposed experiments should provide insight as to whether the observed change in position of hair cell loss after acoustic trauma in early development differentially affects the ability to hear throughout the frequency spectrum. This is of major importance in our attempts to understand how hearing develops. Further, it has broad implications for the effects of genetic or traumatic hearing loss in early life. In addition, if these same alterations in frequency/place coding can be determined in the senescent ear, we will have defined one mechanism responsible for presbycusis. The increasing age of the veteran population, accompanied by increased loss of hearing, makes it imperative to discover as much as possible about the causes of hearing loss as a function of aging. If we see changes in a fundamental auditory process such as place coding, it will have far reaching implications for the prevention and/or rehabilitation of hearing loss in old age.

Effects of Auditory Cues in Computer-Assisted Instruction in Lipreading

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

The purpose of this project is to increase the effectiveness of lipreading instruction for postlingually hearing-impaired adults. Computer-assisted instruction (CAI) is being examined as a way of providing systematic supplementary drill and practice in lipreading.

Among the goals described in previous reports are the following: (i) assembling instrumentation for computer-assisted instruction (CAI), ((ii) development of drill and practice sentences and programming these sentences for CAI in lipreading, (iii) preparation of 12 1-hour lipreading lessons, (iv) surveying the literature on lipreading for a state-of-the-art document on this topic, and (v) examining the effect of auditory redundancy versus linguistic redundancy in CAI in lipreading on the development of lipreading skill.

This report on the past year's progress involves primarily a change in instrumentation and in the programming language used for the supplementary drill and practice sentences which are to be used in conjunction with face-to-face lipreading instruction to be given to postlingually hearing-impaired adults.

The instrumentation we chose for the project included the DAVID Instructional System, developed at the National Technical Institute for the Deaf (NTID) and subsequently assembled and distributed by Von-Tech, Inc., Rochester, New York. It should be pointed out that the original DAVID System designed and used at NTID incorporated a ½-inch videocassette player. Because ¾-inch video cassettes are the standard size in the VA, we were required by VACO to purchase a ¾-inch videocassette player with our DAVID System. It may be that the difference in cassette size led to some problems.

Two primary technical problems caused the DAVID System to be ineffective for the purposes of our project. First, in repeated accessing of specific video frames for the lipreading student, the mechanical process of stop-rewind-stop-replay caused tape slippage which made precise accessing of desired video frames impossible. Second, the time required for the stop-rewind-stop-play sequence was inordinately long, and for the purposes of our project, completely unsatisfactory. As a result, we explored the possible application of a laser videodisc interactive system. The purchase of such a system was approved by the VA Rehabilitation Research and Development Service, and it was ordered and received in the fall of 1983.

The distinct advantage of the laser videodisc interactive system lies in the immediate and precise accessing of any one of 54,000 video frames on the videodisc. This system has been found to alleviate totally the mechanical problems encountered with the previous videotape instructional system. The laser videodisc interactive system consists of the following Sony components: (i) LDP-1000 optical videodisc player, (ii) PVM-12700 color video monitor, (iii) SMC-70 microcomputer, (iv) SMI-7012 dual 3.5-inch micro floppy disc drives, (v) SMI-7073 RGB superimpose module, (vi) SMI-7031 RS-232C interface module, and (vii) cable connectors and other accessories. For controlling sound level in the auditory redundancy condition, a Coulbourn Instruments power supply (S15-05) and programmable attenuator (S85-08) and other accessories are in the system. The auditory signal is routed from the video monitor to the programmable attenuator and then to the external input of the Grason-Stadler 1701 audiometer and finally to TDH-39 earphones in the audiometric test chamber. For programming and editing purposes and for printout of students' responses during computer-assisted instruction in lipreading, an Integral Data

Systems Prism 80 printer is also in the system.

The 12 lists of 25 sentences each of drill and practice sentences have been programmed in Sony BASIC for presentation by CAI in conditions of auditory redundancy and linguistic redundancy.

The future objectives of this project include: (i) the application of the new laser videodisc interactive system for computer-assisted instruction in lipreading, (ii) administering 12 lipreading lessons to postlingually hearing-impaired adults and providing them supplementary drill and practice with CAI in lipreading, (iii) developing new stimulus materials on videodisc and programming these materials for CAI in lipreading, and (iv) applying these materials and procedures to hearing-impaired adults for an evaluation of their effectiveness■

The Modulation Transfer Function as a Predictor of Speech Intelligibility

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The present study applies modulation transfer functions (MTFs) to the prediction of speech recognition. The study assesses the effects of filtering, masking noise, and hearing impairment on both the MTF and speech recognition. The study calibrates the MTF with English speech materials, assesses the effects of hearing impairment, and determines the effect of hearing aids on modulation transfer. Moreover, this study explores the determination of individual MTFs using psychophysical (behavioral) procedures. All previous uses of the MTF as a tool to predict or assess speech-recognition performance have been acoustical in nature and applied only to average performance.

In one experiment, the psychophysical MTF was explored. Ten normal hearing subjects listened to tone pulses embedded in modulated noise, as in our previous report. No background noise was added to the test stimuli for the MTFs; they match the MTFs predicted for a first-order lowpass filter.

The listeners also produced MTFs and speech-recognition scores in two conditions employing background noise (broadband or highpass). A numerical index derived from the MTF, called the speech transmission index (STI) showed a high correlation with the speech scores. The STI will require adjustment for English speech materials. The psychophysical MTF, however, appears promising.

In another phase of the study, 16 normal-hearing young adults have participated in three speech-recognition experiments with results compared to the acoustical STI. In Experiment I of this phase, the subjects made written responses to three tests: the Speech Intelligibility in Noise Test (SPIN); the Nonsense Syllable Test (NST); and the Northwestern University Auditory Test ≤6 (NU-6). Each speech test occurred in one of four signal-to-noise rations (SNRs): quiet; +6 dB, 0 dB and −6 dB. The masking noise for every speech test was the speech babble taken from the SPIN test tapes.

A plot of speech scores versus the calculated STIs of the speech tests from this experiment were marked by L for the low-predictability scores (PL) of the SPIN test, N for the NST, and 6 for the NU-6.

Experiment II of this phase involved only the NU-6 test. The NU-6 lists were presented in quiet and in noise (SNR-+6 dB), with and without filtering (rej. rate-48 dB/octave). The filter functions were 707 Hz, lowpass; 1414 Hz, lowpass; 1414 Hz, highpass; and 2828 Hz, highpass.

A high linear correlation (r-0.90) between the NU-6 scores and the STI was observed in quiet. In noise, the correlation between the scores and the STI was 0.92.

Finally, the last experiment of this phase added reverberation and babble to the NU-6 and NST tests. To calculate the STIs, we used formula for reverberation and added noise.

The results described in this report will be used to recalibrate the STI for each of the speech tests. Then the effects of hearing aids and hearing impairment will be measured for modulation transfer and speech recognition. Speech recognition measures obtained will be compared to those predicted by the acoustical and psychophysical MTFs■

Speech Processors for Auditory Prostheses

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Abstract—The purpose of this project is to design and evaluate speech processors for multichannel auditory prostheses. Ideally, the processors will extract (or preserve) from conversational speech those parameters that are essential for intelligibility, and will then appropriately encode the parameters for electrical stimulation of the auditory nerve on a sector-by-sector basis.

Major tasks in our project include the following: (i) identify and contrast the most promising approaches to the design of speech processors for multichannel auditory prostheses, (ii) build a computer-based simulator that is capable of rapid and practical emulation of all these approaches in software, (iii) design and fabricate a hardware interface that will provide a communication link between the computer and implanted electrodes, and (iv) evaluate promising strategies for speech processing in tests with single subjects so that meaningful comparisons of performance can be made.

At present, tasks ii and iii are essentially completed and work on tasks i and iv is in progress. The tests of task iv are being conducted in collaboration with investigators at the University of California at San Francisco (UCSF). Our colleagues at UCSF are also actively involved in the work of tasks i, ii, and iii. Finally, arrangements have been made to conduct parallel tests at the Duke University Medical Center using procedures identical to those used in the tests at UCSF. We expect to evaluate speech-processing strategies in at least two patients at UCSF and one patient at Duke by the end of this calendar year. The results of these evaluations will be used to identify the best strategies for the patients tested and to guide the design of further experiments for the second year of this project.■

Improvement of Speech Perception for the Hearing Impaired by Enhancement of the Acoustic Features in Speech

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For persons with normal hearing, the perception of speech is a rapid and automatic process. The listener is generally unaware of the physical features in the speech signal by which speech sounds are differentiated. These physical or acoustical features of importance for normal speech perception have been fairly well identified through studies in speech science. It has been found, for example, that individual consonants generally have various acoustic features or cues that could be used for their perception. Some of these cues are primarily temporal in nature, others are spectral, and some are characterized by the presence versus absence of particular kinds of energy in the speech signal.

For hearing-impaired listeners, less is known about the acoustic cues that are used for speech perception. However, recent work has revealed that reduced discrimination for speech acoustic cues may be the basis of deficient speech perception for the deafened. It has been shown that some persons with severe deafness have fairly good discrimination for certain acoustic cues in speech, while others have only limited discrimination for most acoustic speech cues.

Recent work has revealed that particular adjustments to certain acoustic cues resulted in degrated speech perception for hearing impaired listeners with good hearing for speech. Logically, the opposite should occur; if these adjustments to acoustic cues could be reversed and exaggerated, improved speech perception should result. In the laboratory, adjustments to acoustic cues in natural speech have been accomplished by computer analysis and processing. Using these techniques, speech acoustic cues might be enhanced to facilitate speech perception for deafened listeners. This strategy of acoustic cue enhancement could be used in future hearing aids that would employ microprocessing to modify speech patterns. While future hearing aids would amplify speech as do conventional aids, such aids could be adjusted according to a wearer's needs, emphasizing critical acoustic cues that are imperceptable in their natural state for that particular user. Such aids would

have to include pattern recognition circuits that could pick out speech cues and selectively enhance them.

In this research, perception for certain consonants with enhanced cues is studied for deafened listeners. Two experiments are conducted, one focusing on enhancement of only spectral cues and the other focusing on enhancement of both spectral and temporal cues. In each experiment, numerous utterances of selected words that differ in their final consonants are used to evaluate various enhancement values for individual deafened listeners. The utterances are used in selecting the optimum enhancement values for each listener and for training the listeners to perceive consonants with enhanced cues. The optimum enhancements are then processed into utterances of another talker to assess each listener's generalizations for enhanced-cue-use relative to the speech of an unfamiliar talker■

Evaluation of a Physiological Glottal Sensor for Speech Training of the Deaf

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Sponsor: National Institute of Handicapped Research

Persons who are born deaf experience great difficulty in learning to produce intelligible speech. Our research shows that abnormalities in speech breathing and phonatory control are often particularly troublesome for the deaf speaker. Speech teachers must rely primarily on tactile and kinesthetic information in order to correct phonatory/respiratory deficits. However, the inaccessibility and rapidity of movements of the laryngeal structures and the subtleties of phonatory/respiratory coordination, make reliance on such information relatively ineffective for habilitation of speech in most deaf individuals.

Recent technological developments, including development of specialized transducers, and advancements in high-speed, real time computing techniques, now make feasible the development of a phonatory/respiratory modification system for use in teaching speech to deaf individuals. However, efficient and effective use of such technology can be best achieved with well developed instructional programming. The present project therefore focuses on two general areas: the development of a comprehensive computer-based voice monitoring system that will enable deaf speakers to obtain feedback concerning their own phonatory/respiratory behavior; and, the development and assessment of rehabilitative techniques and programs utilizing this computer-based system■

C. Speech Impairment

Tongue Initiated Speech Prosthesis for the Laryngectomy Patient

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

The initial phase of this investigation has been concerned with conducting a thorough and in-depth search of the appropriate engineering and medical literature. While several areas are still under examination, it is apparent that this topic has not received a great deal of attention in the past. The major obstacle to success in producing a suitable prosthesis for this purpose has been the inability to securely anchor a device that is capable of producing adequate power to modulate the air stream generated during speech.

Based on the available literature, recent developments in microelectronics, and the progress being made in the general area of speech recognition and synthesis, this investigator believes it will be possible to produce a device that can provide the desired solution. To accomplish this task, the patient will be required to use the oral cavity as a resonator so as to supplement the output of the prosthesis. This technique should allow the output power of the prosthesis to be held to a minimum, thereby diminishing the impact on surrounding tissue.

Future activity on this project will include selection of the equipment required for speech analysis, evaluation of various available electronic components for use in the prosthesis, and the feasibility of incorporating state-of-the-art speech synthesis technology into the design of the prosthesis. It is expected that these activities will culminate in the delineation of a basic device that can be used both to demonstrate feasibility of the technique and to secure funding for development and testing■

XIV. Miscellaneous

Foreign Body Reaction in the Lung to Intravenously Injected Biomaterials

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

This is the final report on a project in which we have defined a nonsurgical model system for evaluating the cellular inflammatory response to biomaterials embolized to the mouse lung. This system also has proved useful for evaluating the effectiveness of anti-inflammatory agents at various dosages and time periods. The test system consists of divinyl benzene copolymer beads measuring 45 to 53 micrometers in diameter that lodge in the arterioles of the mouse lung after intravenous injection.

Both early and late stages of granulomatous inflammation were observed by electron microscopy progressing from the presence of a very few polymorphonuclear leukocytes at 3 hours to granulomas maximum in size after 48 hours and composed of both polynuclear and mononuclear leukocytes. Granulomas older than 8 days were composed of mononuclear leukocytes almost exclusively. The rate of granuloma formation was quantitated in paraffin sections by tracing the bead and granuloma and measuring the areas with a digitizer attached to a microcomputer. The measurements were stored on a floppy disk, and data from similar experiments merged and analyzed with a statistical program.

This basic model was used to compare the bioreactivity of such materials as poly d, 1-lactide (used for drug transport) and arious formulations of bioglasses (used in joint replacement). The system was quantitatively useful in evaluating the relative effectiveness of both steroidal and non-steroidal anti-inflammatory agents.

Flexible Glow Discharge Polymer Leaching Barriers

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Sponsor: National Institute of General Medical Services

The investigator proposes the deposition of a new polymer onto the surface of a bulk polymer using the glow discharge plasma technique in order to prevent the leaching of plasticizers from the bulk polymer. This project is aimed at the preservation of the physical properties of a polymer that will be placed in service. The investigator proposes to improve the properties of the new polymer by varying its crosslink density. The efficiency of the hydrocarbon plasma polymer as a barrier to leaching of plasticizers from the bulk polymer will be correlated with the degree of crosslinking and the chemical nature of the new surface. It is anticipated that this technique will be valid for coating the inside of small vessel prostheses.

Microsurgical Techniques Applied to Orthopaedic and Hand Surgery

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

We have completed the dog experiments for the second half of the program titled Microsurgical Techniques Applied to Orthopaedic and Hand Surgery. We are reporting the current status on 48 canine experiments studying the radiographic, angiographic, and blood flow data in 48 paired hindlimb orthotopically placed tibia autografts. Forty-eight skeletally mature beagles had both hindlimbs operated on simultaneously. The nutrient artery of the tibia was dissected free using an anterolateral approach. Transverse osteotomies were performed to obtain a 4-cm tibia graft. On the vascularized tibia side, the periosteum was left intact although all muscle attachments were freed. The graft blood flow was retained through the nutrient vessel providing endosteal circulation. The medullary blood flow to the isolated graft was measured using hydrogen washout technique. The contralateral nonvascular graft was harvested similarly except that the nutrient vessels were cauterized and

the periosteum stripped. A seven-hole compression plate was used to rigidly fix both osteotomies on each tibia. Eight dogs were killed at 1 week, 3 weeks, 6 weeks, 3 months, 6 months, and 1 year.

At the conclusion of the experiment, the animals were restudied with graft endosteal blood flow measured using the hydrogen washout technique and then after sacrifice, the perfusion of each limb with barium sulphate-prussian blue mixture via the femoral artery. X-rays were taken postoperatively, at four weeks, and at kill. Radiographic analysis consisted of measurement of graft cortical width, graft width, presence of periosteal and endosteal callus, callus bridging, obliteration of the loosening osteotomy line, and medullary recanalization. Angiographic assessment determined vessel patency and the extent of vascular ingrowth invading the graft.

Our preliminary results have shown that all animals tolerated the procedure and were weight bearing within 2 days postoperatively. All animals were killed on schedule. Vascular grafts demonstrated earlier laying down of periosteal callus (75 percent at 3 weeks) and endosteal callus (81 percent at 3 weeks) as compared to nonvascular grafts (31 percent and 44 percent, respectively). At 6 weeks, 69 percent of vascular grafts showed callus bridging the osteotomy, compared to 19 percent of nonvascular. At 3 months, 87 percent of osteotomies of the vascular side healed and 75 percent had medullary recanalization, while only 43 percent of the nonvascular graft osteotomies healed and 36 percent recanalized. At 6 months, the recanalization rate was 86 percent versus 50 percent vascular to nonvascular.

The degree of osteoporosis measured by changes in cortical width from surgery to kill differed between the groups. The nonvascular graft showed a steady decline in cortical width to -34 percent at 6 months compared to -9 percent in the vascular graft. A vascularized graft blood flow peaked at 3 weeks then decreased and stabilized by 3 months. The blood flow to the nonvascularized graft increased linearly up to 3 months. At that time and thereafter, flow to the vascular and nonvascular grafts was similar. The invasion of vascularity from either end of the graft progressed linearly, but at markedly different rates. The nonvascular graft had vascular invasion at a rate of 0.36 cm per week while the vascular graft was 0.94 cm per week. This increase leveled off following 3 weeks.

We have demonstrated a significant advantage of a vascularized bone graft over a nonvascularized bone graft and the ability to lay down callus, and then the union rates, when bridging large idaphyseal defects. The nonvascular graft showed a greater degree of osteoporosis with time. The increased blood flow to the vascular grafts in the first 3 weeks postoperative seems to be due to a faster rate of vascular invasion across the osteotomy rather than hypertrophy of the nutrient vessels. Segmental bone grafts appear to heal in a fashion similar to segmental fractures, and this process is accelerated in the vascular graft as compared to the nonvascular graft.■

A Program for Evaluation and Monitoring of the Dysvascular Patient

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

The technique of cutaneous pressure photoplethysmography (CPP) reflects physiologic tissue perfusion and does not depend directly on the shape of the arterial pulse of the trunk arteries. As such, this instrumentation may be useful in predicting a successful level of amputation as well as the results of revascularization procedures. In an attempt to determine the usefulness of this technique, we have evaluated a series of patients with atherosclerotic occlusive disease of varying levels of severity and a series of subjects without incidence of occlusive disease.

Twenty-five patients and nine subjects without vascular disease have been evaluated. To evaluate the cutaneous pressure required to maintain a healed stump, 10 of the 25 patients were postoperative amputees. They ranged in age from 35 to 78 years (mean: 63.4) with a follow-up of 3.0 ± 3.4 years. They were all below-knee amputees: five were diabetic and five non-diabetic. Five of the 25 patients were scheduled for revascularization procedures for disabling claudication. They ranged in age from 50 to 70 years (mean: 57) with a follow-up of 3 ± 1.2 months. The remaining 10 patients were prospective amputees and ranged in age from 53 to 76 years (mean: 66.4) with a follow-up of 4 ± 3.1 months. The nine normal subjects ranged in age from 23 to 67 years (mean: 44.4).

In the retrospective amputees, CPP measurements were made at the stump; in the prospective patients and normals measurements were made at four locations: 10 centimeters proximal to the knee joint, at mid-calf, over the dorsum of the foot, and at the chest.

CPP senses the blood flow in the skin at various

skin-bearing pressures using a handheld probe. The photoplethysmograph consists of a sensing probe containing a small light source and a photosensitive cell that responds to light reflected from the cutaneous vascular bed. The photoplethysmograph, connected to a recorder, prints out a permanent waveform. The skin-bearing pressure probe is calibrated using a known force loading on the bearing surface of the probe. The skin-bearing pressure is shown on a digital display directly in mm Hg while the waveform is printed.

The probe initially is placed at the site desired and a waveform is obtained. With the manual application of gradually increasing pressure, the waveform is obliterated. Pressure is then gradually released and the pressure reading at the point where the photoplethysmographic waveform returns is recorded as the cutaneous pressure.

Most techniques of blood pressure measurement in the extremities are designed to measure pressure in the main arterial pathway. For example, Doppler segmental pressures record systolic pressure at various levels of the extremity by means of a probe placed over an artery, most frequently the posterior tibial artery. The technique of cutaneous pressure photoplethysmography (CPP), however, does not entail use of a main artery. The basis of this technique, similar to that detailed by Holstein, is measuring skin perfusion pressure as the amount of external pressure required to halt isotope washout. Increases are seen in tissue perfusion pressure, as well as in the venous pressure and the microcirculation in general, in an attempt to overcome an applied external pressure. Blood flow ceases with sufficient external pressure and tissue pressure becomes zero, thus making venous pressure equal to arterial pressure. The external pressure at this point is a reflection of the pressure head in the main supply artery. Thus, if local venous pressure approximates zero when external pressure is applied, that external pressure, in mm Hg, is a measure of the local perfusion pressure.

In normals, there is no gradient in cutaneous pressure from the chest to the dorsum of the foot; cutaneous pressure at each level of the leg was higher than that of the chest. In patients with vascular disease, marked gradient in cutaneous pressure occurs from the chest to the dorsum of the foot. Cutaneous pressure is much lower in the presence of rest pain, gangrene, or ulceration than with intermittent claudication. A cutaneous pressure of about 50 mm Hg is required to assure wound healing.

CPP is effective in differentiating normals from diseased patients, the severity of the vascular disease, and the optimal level for amputation. This study is ongoing; a preliminary report on the use of CPP has been submitted for publication.

A Life-Span Approach to Product Design and Development for the Aging Population

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Sponsor: Veterans Administration Rehabilitation Research and Development Service

Problem—The demography of the United States is changing rapidly as the older segment of the population increases. As a result, the needs, wants, and capabilities of the average user are changing too. This will soon necessitate the reassessment of the standards by which products are now developed and evaluated. The human factors profile currently used by designers is based on the ergonometric and anthropometric characteristics of a male 21-30 years old. Less than 10 percent of all older adults match this profile. There is a need for a human-factors profile that takes into account the human values and the physical characteristics of the aging population.

Hypothesis—We hypothesize that technology which is developed through an interactive process and coupled with an approach to design and development based on a lifetime continuum, will be more appropriate to, and therefore more accepted by, the end-user population. This interactive process requires user involvement at all stages of the development cycle. It is believed that user-focused research will insure a well-defined need statement, which is necessary to optimize the relationship between human and machine and will aid in the diffusion process.

Approach—The Interactive Evaluation Model is used to focus on a life-span approach to product design and development. The project seeks to:

1. Involve student design engineers and older people in intergenerational needfinding and design;
2. Provide students with a broader perspective to design and development;
3. Develop methodologies to better educate engineering design students to meet the needs of older users;
4. Develop a model from structuring communication between users and designers;

5. Develop criteria for evaluation of marketed assistive devices;
6. Provide feedback to manufacturers of assistive devices;
7. Facilitate interaction between academia, industry, and government; and,
8. Identify new projects which promise to benefit the aging through the application of microcomputer technology.

Status—The VA RR&D Center and the Stanford University Mechanical Engineering Design Division have collaborated on two student projects in the past year. Both were designed to highlight the needs of the elderly and to educate the students in a life-span approach to design. In one of the VA/Stanford projects, the interaction between academia, government, and industry was of primary concern. This interaction is continuing as the manufacturer considers the student ideas in the upcoming redesign of their product.

In the evaluation effort, retired professionals are involved in the identification of needs and definition of appropriate technology for their peers. Currently a computer class at one of the local senior centers (average age of the programmers: 69) is helping in the evaluation of a commercial robot for use by the infirmed. Other seniors are serving as advisors and community liaisons for a project in "needfinding" at Stanford. The results of this research were scheduled to be presented at the 30th Annual Meeting of the Western Gerontological Society in March of 1984■

Rehabilitation Engineering Center for Product Evaluation

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Sponsor: National Institute of Handicapped Research

Evaluation of technology is the core area of study for the Southwest Research Institute-Rehabilitation Engineering Center, which was funded in May 1983. The center's primary mission is to test, evaluate, and disseminate information concerning the suitability and application of new rehabilitation equipment to rehabilitation clinicians and consumers.

The center has accomplished a number of tasks during its first year of operation leading to the establishment of a viable center for product evaluation. These tasks include an international assessment of prior rehabilitation evaluation experiences, development of a standard methodology for product evaluation, and participation in a cooperative process for selecting evaluation items.

Two product evaluations were begun. These products are the Storable Crutch, developed through the Stanford Children's Hospital REC program, and the Automatic Leg Bag Emptier, developed through the REC program at Rancho Los Amigos Hospital. Engineering tests and user pretests of both items have been completed and clinical evaluations are in progress through the University of Texas Health Science Center, Department of Physical Medicine.

The project staff has developed and identified numerous channels through which to disseminate rehabilitation technology information and make potential users of such information aware of the REC. Specific tasks include development of the Tech Eval newsletter to be used for reporting, announcing, and presentation of instructional information related to technology evaluation. Additional dissemination tasks accomplished include article contributions to various publications, paper presentations, panel participation, booth exhibits at numerous conferences, and visits to rehabilitation programs and facilities.

Cooperation has been developed with the REC at the Electronic Industries Foundation (EIF), which shares the responsibility for the total mission of evaluation of technology and stimulation of industry. EIF will focus on selecting products to be assisted by both programs and will interact with prospective manufacturers to develop the product for market, while this center will concentrate its resources on developing sound engineering and clinical testing procedures aimed at informing the intended purchaser(s).

As the center begins its second year of operation, plans call for intensifying efforts to identify and catalog prior and current experience in evaluation and testing of rehabilitation devices and methods. The center also will work toward attracting commercial and nongovernmental support for evaluation service■

Rehabilitation Information Project

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Problem—The rehabilitation community, while sharing many common aims, means, and professional commitments, is also characterized by the geographical dispersion of its many members, and by the differences in professional specialties and levels of training inevitable in an essentially multidisciplinary field. With growth, this community has developed some special needs.

Among these emerging needs is one defined by the broad area of information exchange. Particular aspects are the need for better intracommunity communication, and the need for consumer involvement.

As important as these needs are, the current means for accomplishing them appear inadequate, as the literature suggests. Without efficient communication, informationally isolated islands of community members persist. As a result, research activities and funding are often duplicated, new techniques and devices are not widely disseminated, the experiences of members are not communicated, and the intended users of aids do not have a voice in their development.

Significance—An ideal solution to this situation would be a mechanism that enabled rehabilitation community members to make informed decisions based upon an enhanced ability to interact in an effective and synergistic manner. If such a mechanism existed, the barriers that distance, schedule, finances, ability, and possession of equipment impose on information access would be reduced, permitting wider participation by all. However, such a solution does not now exist.

Background—The RR&D Center and the VA's Western Blind Rehabilitation Center (WBRC) have cooperated on numerous projects during the past several years. These projects include a joint VA/Stanford project to develop a personal information system for the visually impaired. Preliminary work conducted at the RR&D Center has demonstrated the feasibility of a universally accessible information system serving the rehabilitation community. The WBRC has operated the Electronic TeleCommunications, Education, Training, Evaluation, and Research Activity (ETCETERA) and more recently the Computer Training and Education Program (C-TEP) which provides a community locus for training and research on computer-based aids for the visually impaired. Other local resources, including the Sensory Aids Foundation, provide a vocational setting for the practical application of this training.

While other systems such as Abledata, Special Net, Wellnet, and Handicapped Education Exchange offer information in computer form, they all require the use of a modem and terminal or computer. A system that requires no special equipment for access, provides interaction between users, is easy to learn and use, and is equally suited for all those interested in rehabilitation issues would promote a significant improvement in information dissemination and informed decision making.

Hypothesis—It is hypothesized that a computer-based information system accessible by Touch-Tone input and machine produced synthetic speech can be developed and employed within the local rehabilitation community to foster increased information exchange and consumer involvement. The system's specific goals are to: improve employment opportunities, reduce social and economic dependence, improve information dissemination, and improve communication among rehabilitation researchers.

Approach—The goal of this project is to develop a universally accessible mechanism. Its potential users are both agencies and individuals. Federal and private organizations such as the Veterans Administration (RR&D and WBRC Centers) and Sensory Aids Foundation will be involved initially. Individual participants include those with disabilities, physicians, manufacturers, therapists, policy makers, employers, those seeking employment, educators, and senior citizens.

The information in this system would reside in a telephone-accessible central storehouse from which users could select a specific subset for decision making, evaluation, interaction, inquiry, or response. For example, one would be able to make a purchase decision between several functionally identical devices based upon the centrally held documented experiences of others.

The central system would manage data, convert selected information to synthetic speech, and transmit it over the telephone. The user's Touch-Tone keypad could provide unrestricted interactive input. In operation, one would telephone the system and respond to a series of spoken prompts with Touch-Tone button presses. The system would decode these

keystrokes and select information to be spoken from its store. Messages could be sent to the system by employing a two-button entry scheme.

In such a system, both information retrieval and generation could be performed by users without their purchasing specialized equipment (terminal and modem communication would also be supported, to accomodate those with impaired hearing). A human information specialist to aid new users and provide advanced assistance for others would reduce demands upon the user/system interface's versatility.

To achieve enhanced communication, there could be several methods of information exchange within the system. On-line newsletters could facilitate the dissemination of information from a central organization to its members. Separate publications would be created to cater to the interests of the spinal cord injured, visually impaired, and those desirous of data on vocational aids. An electronic employment service could also be implemented, acting as an information node among prospective employees, potential employers, and an employment counselor. A continuing advertising section on the system would provide users with an up-to-date list of jobs available and situations wanted. Interviews could be conducted and resumes exchanged in privacy over the proposed system. Finally, Design Circles will allow consumers to interact with designers at all stages of development of new products. Meetings of the group could also include both consumers, potential manufacturers, and health care professionals.

Although this one system could not possibly serve the entire national rehabilitation community, it could serve as a local model for other identical microcomputer-based systems, or for a national network connected to a large computer.

Status—Several speech synthesizers have been acquired and their characteristics have been investigated. Microcomputer hardware systems have been surveyed for their suitability for this project and a database software search has begun.

While the need and problem have been determined, a concerted effort on this project awaits funding. A proposal requesting funding for this project has been submitted for VA merit review. If approved, the 2-year project would receive initial funding in October 1984■

Topical Anesthesia and Muscular Hypertonicity

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Sponsor: Liberty Mutual Insurance Company

Muscular hypertonicity is among the most disabling symptoms affecting patients with central nervous system disorders. It appears as spasticity in patients with stroke or cerebral palsy and as muscular rigidity in patients with Parkinson's disease. Increased joint stiffness during movement, coupled with muscle weakness in the upper and lower extremities, reduces these patients' functional capabilities. Pharmaceutical treatments are not often effective.

Our recent neurophysiological studies led us to develop and test a new treatment technique using topical anesthesia. Details of the double-blind research design involving the topical anesthesia and a placebo were reported in our 1982 Activities Report.

A controlled study of chronic stroke patients demonstrated that 5 out of 10 treated with topical anesthesia on the lower limb had short-term benefits, requiring less time to complete ten rapid repetitive movements of the limb joint. Longer-term treatments, consisting of three sessions per week for 1 month, yielded even better results: all nine patients tested in a long-term application achieved faster movement capability at the knee joint. At the elbow joint, three patients showed substantial improvement immediately after treatment and four showed a substantial improvement in the long-term treatment.

During the past year, we conducted a controlled study to measure the ground reaction forces on the affected and nonaffected legs of stroke patients and obtained stabilograms (pattern and degree of sway of the center of gravity) before and after immediate and long-term application of topical anesthetic. We observed an improving trend in all measures of gait immediately after anesthesia. The long-term treatment resulted in considerable progress toward normal values by the end of the treatment.

Numerous health professionals have expressed interest in using our technique and have written us for information. Since we wanted to evaluate the perceptions, practical experience, clinical findings, and complaints of health professionals who applied our techniques, we sent a questionnaire to all who had received our information. The responses were numerous and favorable. Of the 230 questionnaires that we sent out, 13.4 percent indicated that they had used the

technique on at least 109 patients. An overwhelming number of these reported improvements in their spastic patients' movement capabilities.

Topical Anesthesia and Parkinson's Disease

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Parkinson's disease is a movement disorder of the central nervous system and affects about 500,000 people in the United States. Neurochemical studies of patients with Parkinson's disease show an imbalance in the brain neurotransmitters, dopamine, and acetylcholine. But since causal factors are still unknown, rehabilitation plays the major role in functional recovery for these patients. Surgical, medical, and physical therapies all have been used with varying success.

Since we had demonstrated the usefulness of the topical anesthetic technique in mitigating symptoms of spasticity in other patients, we began a pilot study during 1983 to test the efficacy of a topical anesthetic spray with people suffering from Parkinson's disease. Individuals with this disease tend to walk with difficulty due to muscular rigidity. They take smaller steps at slower speeds and are more rigid while walking as a result of diminished central nervous system control of their peripheral musculature. They also usually exhibit some resting tremor and difficulty with other activities of daily living.

Our controlled double-blind study measured ground reaction forces, step length, and the temporal components of gait. Specific variables included stride, support, swing, step times, and sway patterns during quiet standing.

Preliminary results demonstrate some improvements in the ground reaction force pattern as the foot strikes the ground. Before treatment, as the weight-bearing phase of their gait began, patients exhibited force-vector profiles indicating reduced progression of the center-of-pressure of their weight. Weight acceptance was slow and showed abnormally sequenced force vectors indicating an abnormal movement of the body. After application of the topical anesthetic, their profiles shifted toward a normal pattern. We observed no measurable changes in the temporal parameters of gait. Electromyographic recording may help us to elucidate the factors leading to the changes. More subjects need to be tested before we can make any informative conclusions.

Topical Anesthesia with Normal Subjects

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Sponsor: Liberty Mutual Insurance Company

We have previously published reports with evidence for increased excitation of motor activity in the spinal cord following desensitization of the skin by topical anesthetics. These increases have been associated with alterations in the gait of spastic patients.

In the past year, we have investigated these phenomena in the gaits of normal subjects. We tested six normal subjects on an instrumented walkway before and after the application of a topical anesthetic. Vertical ground reaction forces were measured from a computer-controlled force plate while the subject ambulated or walked in place. (Walking in place was tested because of the ease with which multiple steps could be recorded on a single-force platform.) Foot switches attached to the sole of the foot at the heel and toe recorded the foot contact history. A topical anesthetic was sprayed to all skin areas of one lower limb except for the skin overlying the front of the shin and the sole of the foot. Measurements were repeated at 15-minute intervals up to 1 hour after the anesthetic.

We found increases during gait and while walking in place in the vertical ground-reaction-force peaks following topical anesthesia; no consistent change occurred in the timing of foot contact or in the walking speed. These effects observed during gait and while walking in place are consistent with an increased excitability of the spinal neurons related to the extensor muscles. Therefore, the motor control of stereotyped movement patterns, such as those occurring in gait, can be modified by reducing the skin's sensory input.

The observed effect of topical anesthesia on ground reaction forces was more dramatic and more consistent for walking in place than for gait. This may have resulted from the greater stretch during walking in place to the extensors of the ankle; greater stretch occurs with the toe-heel sequence of walking in place than with the heel-toe sequence normally used in gait. Marching in place thus offers a useful new method of gait analysis.

Sponsoring Agencies and Organizations

American Foundation for the Blind

New York, New York 10011

Douglas R. Maure, Director, Technical Development Department

The American Foundation for the Blind (AFB) began in 1981 to develop a new cane, a program supported in part by a contribution from the Veterans Administration. The Superfold Cane Development Program took approximately three years, involving many different types of experiments and analyses.

The foundation first commissioned an evaluation of the acoustical and vibratory characteristics of folding canes. The results of this study indicated that material selection has little effect on the vibratory characteristics of the cane because the rubber handle absorbs most of the high frequency. This seemed to indicate that if a cane could be fabricated without a rubber handle, and made of graphite (a superior material for transmission of vibrations), a great deal more feedback via the cane would result. Factors considered in the experimental designs were a strong handle-connecting joint, interchangeable cane tips for variations in acoustical reflections, easier ways to repair and replace individual parts of the cane, stronger metal parts, and a stronger cord.

A report on the various cane designs developed and tested to achieve these goals is in section **XIII. Sensory Aids, A. Blindness and Low Vision, 2. Mobility Aids** under the title of Superfold Cane Development Program■

American Paralysis Association

McLean, Virginia 22101

Kent Waldrep, President

The American Paralysis Association serves as a research contractor whose resources come from fund-raising projects and from donations. The association's research program has, until recently, concentrated on research projects that hold the greatest promise for achieving a cure for central nervous system trauma-related paralysis in humans. The scope of the association's efforts has broadened, however, to include all traumatic injuries to the central nervous system — brain and spinal cord. Since such central nervous system research is interdependent, future support and coordination of brain and spinal cord injury research should benefit and expand the association's mission.

Project reports included in this issue are in section **IV. Spinal Cord Injury**, under subheads **A. General Rehabilitation, B. Medical Treatment**, and **C. Spinal Cord Regeneration**. They are:

- Demographic and Economic Studies;
- Evoked Potentials Study;
- Effects of Low-Power Irradiation on Clonus and Spasticity in Spinal Cord Injured Persons;
- The Effect of Electrical Stimulation of Muscles on the Cardiovasculatory System;
- Monitoring of Post-Injury Changes;
- Tissue Implant Studies;
- Collagen Matrix Implant Studies;
- Omentum Transposition Study;
- Cortico Spinal Neuron Studies;
- Effects of Application of Direct Current on Regeneration of Nerve Cells; and
- Use of PF in Stimulation of Spinal Cord Neuron Development■

Research Unit for the Blind Institute for Bioengineering Brunel University

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Middlesex UBI 3PH, England

Dr. J.M. Gill, Director

The goals of the Research Unit for the Blind are to develop methods of increasing access to information,

and help make these methods available to the visually disabled. Such developments include embossed maps and diagrams, a Braille and Ink-Print Text-Processing System, a Braille and Speech Information System, and braille bank statements. The research unit publishes a newsletter designed for researchers interested in applied research on braille. The unit also maintains three databases: an international directory of agencies for the visually disabled; an international register of research on visual disability; and, an international survey of aids for the visually disabled.

The Research Unit for the Blind is further described in the project reports under section **XIII. Sensory Aids, A. Blindness and Low Vision, 3. Reading Aids**. The report is titled Reading Aids for the Blind■

Cerebral Palsy Research Foundation of Kansas, Inc., and Wichita State University College of Engineering

Rehabilitation Engineering Center
Wichita, Kansas 67208

John F. Jonas, Jr.; John H. Leslie, Jr.; and Roy H. Harris, Co-Directors.
Leonard H. Anderson, Director of Engineering

The Wichita Rehabilitation Engineering Center, a collaborative effort of the Cerebral Palsy Research Foundation of Kansas, Inc., and Wichita State University, College of Engineering, believes that severely handicapped persons can be productive on the job and at home through the interaction of engineering. To validate this belief, the center supports 13 individual projects related to the following three research areas:

1. Standards and assessment indicators for the worksite, including potential productivity on the job and, as an adjunct, the development of time standards to be utilized as performance criteria for hiring handicapped persons. A fundamental element of job matching is the determination of the physical abilities of the person being considered for employment, according to the center's working philosophy.

2. Worksite modification to enhance employability. This segment of the research investigates the utilization of robotic arms by disabled people in productive environments, the analysis of available motions of head, mouth, and hand stick users with particular application to keyboard designs, the design of a handwand with grasp and release capabilities, and other studies related to the productive employment of severely handicapped persons. The development of models for employment of this segment of the population is extremely important, the center believes, since they are traditionally judged by rehabilitation professionals to be non-feasible for employment.

3. Development of independent living skills to enhance employability. Cerebral palsy research has shown that the life of a severely handicapped person is a tightly integrated continuum of services. The purpose of the Wichita Rehabilitation Engineering Center is to provide research information through engineering methodology to ensure that these services are cost effective.

The 13 projects in the three categorical areas are complementary and provide a continuum of research devoted to outcome oriented results. One of these projects, Headwand with Grasp and Release Capabilities, is summarized in section **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**■

Department of Education National Institute of Handicapped Research

Washington, D.C. 20024

Alton Hodges, Acting Director

The National Institute of Handicapped Research provides support for national and international programs of comprehensive and coordinated research regarding the rehabilitation of handicapped individuals. The institute is a disseminator of information about developments in rehabilitation procedures, methods, and devices that may improve the lives of mentally and physically handicapped people, especially those who are severely disabled. An important aspect of research supported by the institute is finding ways to integrate the handicapped into independent and semi-independent community life.

One activity of the institute is the Research and Demonstration Program, through which grants and contracts are awarded to investigate unsolved problems relating to vocational rehabilitation and other services and specific needs of the handicapped. Another are the institute's Rehabilitation Research and Training Centers, where research is carried out in priority areas. From these centers research knowledge is transposed into usable products for rehabilitation practitioners and information is disseminated into existing service delivery programs.

The institute supports Rehabilitation Engineering Centers in the U.S. and abroad to develop methods of applying advances in scientific and medical knowledge with regard to the problems encountered by handicapped people. The centers are encouraged to establish official working relationships with institutions of higher learning in medicine, engineering, and related sciences. The institute's international research, demonstration, and training program serves to share information about advances in rehabilitation among professionals both in this country and abroad.

A special area of interest is a program the institute conducts for spinal cord injury research and demonstrations and the dissemination of information about advances in this area, as well as other special efforts to assist spinal cord injured persons. The rehabilitation needs of specific populations such as ethnic or racial minorities, those living in isolated, rural areas, and those who are very old or very young are addressed through these projects.

Projects reported in this issue have been in progress at locations throughout the U.S. and at research centers abroad. They are listed alphabetically by the name of the institution where projects have been carried out.

Medical Rehabilitation Research and Training Center in Spinal Cord Dysfunction
Spain Rehabilitation Center
University of Alabama in Birmingham

Birmingham, Alabama 35233

Samuel Stover, M.D., Director

The following project reports will be found in **IV. Spinal Cord Injury, B. Medical Treatment**:

- Determinants of Renal Function Alteractions During Long-Term Follow-up in Patients with Spinal Cord Dysfunction Using Radionuclide Procedures;
- Effectiveness of Prophylactic Antimicrobial Therapy in Patients with Spinal Cord Injury;
- Urinary LDH Fractions for Localizing Site of Urinary Infections in Patients with Spinal Cord Dysfunction;
- Didronel in the Prevention of Heterotopic Ossification Following Spinal Cord Injury; and
- Dermal Fibrosis in Spinal Cord Injury Patients■

Research and Training Center in Spinal Cord Dysfunction
Baylor College of Medicine and The Institute for Rehabilitation and Research

Houston, Texas 77030

William A. Spencer, M.D., President

The following project reports are found in **IV. Spinal Cord Injury, A. General Rehabilitation**:

- Outcome Studies Pertinent in the National Spinal Cord Injury System;
- Development of a Reconditioning Exercise Program for Patients with Paraplegia;
- Assessment, Development, and Clinical Applications of Strategies to Coordinate Services for Spinal Cord Injured Clients after Discharge;
- Documenting and Utilizing Programs to Provide Community Adustment and Independent Living Services for Persons with Spinal Cord Injury; and
- Vocational Evaluation for Quadriplegics with a High School Education or Less.

In the same section, under **B. Medical Treatment**, are the following project reports:

- Effects of Spinal Cord Injury on Drug Metabolism;
- Collagen Dysfunction in Quadriplegia;
- Neuroaugmentive Procedures for Modification of Abnormal Motor Control in Patients with Spinal Cord Injury; and
- Longitudinal Assessment of Physical Therapy Factors that Affect Quality of Life of Persons with Spinal Cord Injury■

Electronic Industries Foundation Rehabilitation Engineering Center

Washington, D.C. 20006

John J. Walsh, Director Rehabilitation Engineering Center

Under a grant from the National Institute of Handicapped Research, the Electronic Industries Foundation formed the Rehabilitation Engineering Center in 1983 for the purpose of improving the commercial availability of assistive devices and systems designed to aid disabled people. The center results from the recognition that many worthwhile products have been developed through government and private research efforts but, for a variety of reasons, have never been commercially produced and made available to disabled individuals who may benefit through their use.

To address this concern two primary research core areas have been developed at the center: (i) commer-

cialization advancement and, (ii) evaluation of technology. The center will manage the evaluation of selected devices that have been developed by currently operating research and design programs. Following laboratory, clinical, and field testing, devices determined feasible for production will be advanced through a commercialization process involving private industry in production, marketing, and distribution. This center's activities will be structured to complement, not replace, activities underway in other centers.

The center employs a professional staff with special competencies in engineering, technical evaluation, product management, and marketing. An advisory committee comprised of individuals from private industry, general rehabilitation, rehabilitation research, and rehabilitation consumers has been formed and will participate in planning and evaluation of the center's activities and in validation of the need for proposed research■

Faculty of Electrical Engineering
Universitet Beograd
YU-11000 Beograd

Dr. Dejan Popovic, Principal Investigator

Research activity on this project is taking place at the Faculty of Electrical Engineering, Belgrade, and the Rehabilitation Institute "Dr. Miroslav Zotovic," Belgrade. The work is supported by the National Institute of Handicapped Research and the Serbian Science Community in Belgrade. The project report, Technical and Clinical Evaluation of the Self-Fitting Modular Orthosis, appears in the **II. Orthotics, A. Lower Limb** section of this publication■

Fauji Foundation Medical Centre
Department of Prosthetics and Orthotics
Rawalpindi, Pakistan

Salim A. Khan, F.R.C.S., and Rana Azim, M.B.B.S., Principal Investigators

The project conducted at the Fauji Foundation Medical Centre, Effectiveness of Prosthetic and Orthotic Devices Used in Pakistan, is reported on in section **1. Amputations and Limb Prostheses, A. General**.

A related project has been carried out at the following location.

King Edward Medical College
Orthopaedic Department
Mayo Hospital
Lahore, Pakistan

Naseer Mahmood Akhtar, F.R.C.S., Principal Investigator

This project, Evaluation of the Effectiveness of Modern Prosthetic/Orthotic Techniques and/or Hardware in Pakistan at King Edward Medical College, also will be found in section **I. Amputations and Limb Prostheses, A. General**■

The Gallaudet Research Institute
Gallaudet College
Washington, D.C. 20002

Raymond Trybus, Dean

Three projects conducted at the Gallaudet Research Institute and sponsored by the National Institute of Handicapped Research are reported on in section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**. They are:

- Design and Evaluation of a Wearable Vibrotactile Aid for the Deaf;
- Improvement of Speech Perception for the Hearing Impaired by Enhancement of the Acoustic Features in Speech; and
- Evaluation of a Physiological Glottal Sensor for Speech Training of the Deaf■

Government General Hospital
Department of Orthopaedic Surgery
Madras-600 003, India

T.K. Shanmugasundaram, M.S., M.Ch.Orth., F.R.C.S., Project Director and Principal Investigator

This is a paraplegic project which has been completed during the past year. It is reported in section **IV. Spinal Cord Injury, A. General Rehabilitation**, under the title of A Research and Demonstration Project for Rehabilitation of Paraplegics in Madras■

Rehabilitation Engineering Center Harvard University/Massachusetts Institute of Technology

Cambridge, Massachusetts 02139

William Berenberg, M.D., Director

The Harvard University/Massachusetts Institute of Technology Rehabilitation Engineering Center has 12 years of experience as a closely coupled clinical and engineering setting for research on behalf of patients with physical disabilities, and has served as a regional consultation center for objective evaluation of the consequences of both conservative treatment and surgical therapy. The clinical center is located at the Children's Hospital Medical Center. Participating organizations include Children's Hospital Medical Center, Harvard Medical School, and Massachusetts Institute of Technology.

The research program consists of a number of interrelated projects consistent with the central objective, quantitative measures of the functional performance of handicapped persons, and of the technology to ameliorate their disabilities.

Projects are reported on in section **V. Functional Assessment**:

- Quantification of Mobility Performance for Functional Assessment, Diagnosis, and Therapy of Neuromuscular, Skeletal, and Synovial Joint Dysfunction;
- Quantification of the Functional Capacity of Upper Limb Amputees; and
- Predictive Assessment in Prescription of Functional Aids for the Motor Disabled.

Additional projects are described in section **VI. Biomechanics, C. Human Locomotion and Gait Training**. They are:

- Quantitative Interpretation of EMG During Gait;
- Mechanical Energy Analysis of Abnormal Gait;
- Objective Interpretation of Gait Analysis Data; and
- A Self-Contained Portable Force and Movement Measurement System to Aid Diagnosis and Rehabilitation of Human Movement Disorders■

Research and Training Center on Independent Living University of Kansas

Lawrence, Kansas 66045

James F. Budde, Director

The mission of the Research and Training Center on Independent Living (RTC/IL) is to develop and disseminate practical techniques to enable people with severe disabilities to live more independently. These new social technologies include service-delivery systems, skill training methods, and relevant information that improves human services and community support for people with disabilities.

This is the only research and training center devoted exclusively to independent living. Its foremost constituency is the network of more than 300 independent living programs throughout the country and the consumers of their services. RTC/IL consumers include independent living specialists and administrators, vocational rehabilitation professionals, and other human service providers. In addition, technical assistance is provided to consumer organizations involved with independent living centers.

Research is carried on in three core areas: monitoring the state of independent living, facilitating consumer self-help, and improving independent living services.

Projects reported in this issue are in section **IV. Spinal Cord Injury, D. Independent Living for the Severely Disabled**. They are:

- Conducting a State Policy Study to Help Develop New Options for Independent Living;
- Human Concerns of Disabled Persons: Developing New Methods for Addressing Common Community Concerns, and Developing a Human Concerns National Data Base;
- Effects in the Family on Independence;
- Utilizing the Concerns of Disabled Consumers to Assess the Impacts of Independent Living Programs;
- Systematic Approaches to Consumer Involvement: Training Citizens with Disabilities in Community Leadership;
- Support for Families: Family Problem Solving;
- Management Procedures in Attendant Care: A Training Model for Disabled Consumers;
- Human Dignity Project;
- An Analysis and Review of Peer Counseling Provided by ILCs;
- Development of an Impact Evaluation Package for Independent Living Centers;

• Encouraging Private Sector Initiatives to Improve Community Accessibility;
• Nongovernmental Funding Alternatives; and
• Promoting Community Support for Independent Living■

Rehabilitation Engineering Center for Personal Licensed Vehicles Louisiana Tech University

Ruston, Louisiana 71272

Duane F. Bruley, Ph.D., Project Director
Paul N. Hale, Jr., Ph.D., Deputy Project Director

In September of 1983, a cooperative agreement between Louisiana Tech University and the National Institute for Handicapped Research established a Rehabilitation Engineering Center for Personal Licensed Vehicles. This agreement funded a 4½-year project for research, development, and formulation of national standards. Objectives of the center are based on these research priorities: (i) the design of assistive devices and control systems; (ii) the analysis of control devices for safety, reliability, and ergonomics with the aim of establishing national standards; (iii) assessment of the disabled individual to create an appropriate match of adaptive devices to the client's measured abilities; and, (iv) expansion of the existing driver training program to habilitate and rehabilitate disabled drivers for safe, reliable performance on highways and streets.

The center will continue, and expand, research and development of assessment techniques, adaptive devices, and driver training strategies being conducted at the present time in the Department of Biomedical Engineering.

The project, Building a Data Base for Standards for Personal Licensed Vehicles, is described in section **IV. Spinal Cord Injury, H. Personal Licensed Vehicles**■

Rehabilitation Engineering Center for the Quantification of Function/Performance University of Minnesota Hospitals

Minneapolis, Minnesota 55455

G. Gullickson, Jr., Ph.D., and
R. Patterson, Ph.D., Project Directors

The Department of Physical Medicine and Rehabilitation and the Department of Mechanical Engineering at the University of Minnesota have joined to develop quantititative means of assessing limb and truncal motion and motor function in the normal and disabled populations.

The strength component of the motor evaluation of the physically handicapped individual is performed by the clinician in a qualitative manner. As a result, the amount of motor dysfunction and the effect of prescribed therapeutic programs cannot be quantified directly. Development of methods and equipment to quantitatively assess motor function using advanced technology will permit accurate assessment of an individual's status, as well as the effectiveness of therapeutic modalities.

Goals of this research are: (i) to develop computerized isometric instrumentation to assess ROM, strength, and endurance; (ii) to validate these instruments and methods; (iii) to establish performance criteria with respect to functional requirements for performing various activities; and, (iv) to prepare such equipment for use by appropriate service providers in the rehabilitation process.

Reports on these projects are in section **V. Functional Assessment**, under the titles of:
• Quantification of Motor Performance: Muscle Strength and Endurance Testing; and
• Quantitative Measures for Assessing Therapeutic Effectiveness■

Rehabilitation Research and Training Center on Blindness and Low Vision Mississippi State University

Mississippi State, Mississippi 39762

Steven D. Machalow, Ph.D., Research Director

Mississippi State University, in cooperation with the University of Mississippi Center for Handicapped Research and Training and the University of Mississippi Medical Center, established the Rehabilitation Research and Training Center on Blindness and Low Vision (RRTC/BLV) during October 1981. The mission of the RRTC/BLV is to identify, assess, and augment services intended to facilitate the employment and career development of blind and visually impaired persons. The core research question being addressed by the RRTC/BLV is: How effectively do each of the career development services provided at each service delivery site contribute to the employment of blind persons?

The research reported in this issue receives its basic funding from the National Institute of Handicapped Research, with secondary contributions provided by Mississippi State University.

Descriptions of current projects are in section **XIII. Sensory Aids, A. Blindless and Low Vision, 1. General**. Titles are:

- Demonstration of a Low Vision Aid Clinic as an Employment Enhancement Technique;
- Industrial Services Program Model for Sheltered Workshops for Legally Blind Workers;
- Assessment of Current Career Development Intervention Services and the Needs of the Blind and Severely Visually Impaired Individuals;
- Functional Outcome for Blind/Severely Visually Impaired Clients of State Rehabilitation Agencies;
- Illumination Level and Color-Contrast Studies;
- Development of Electromechanical Vocational Assessment Technology for Finger Dexterity and Hand/Foot Coordination;
- Vocational Assessment of Blind, Partially Blind, and Severely Visually Impaired Persons;
- Training Opportunities Profile for Visually Impaired Persons;
- Prevocational Work Ability and Success Acquisition Training of Deaf-Blind and Other Multiply Handicapped Individuals;
- Assessment of Eye-Hand Coordination and Manual Dexterity Under Different Illumination Level and Contrast Conditions; and
- Selected Career Development Factors and Outcome of Vocational Rehabilitation Services Provided Middle-Aged and Older Blind Persons■

Department of Rehabilitation Medicine New York University Medical Center

New York, New York 10016

Joseph Goodgold, M.D., Chairman Department of Rehabilitation Medicine, and Director, Rehabilitation Medicine Services

Project reports included in this issue follow.

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 4. Other**:

- The Effect of Electrical Stimulation and Passive Stretch on Peripheral Nerve Disorders.

In section **V. Functional Assessment**:

- Investigation Regarding the Optimal Application of Technology-Based Treatment Modalities Applied to Assessing and Ameliorating Motor Defects.

Two projects receiving funding from the **Muscular Dystrophy Association** as well as NIHR are reported in section **XII. Respiration (Muscular Dystrophy)**. They are:

- Inspiratory Muscle Fatigue as a Cause of Respiratory Insufficiency in the Muscular Dystrophies and other Neuromuscular Diseases, and
- Respiratory Load Compensating Mechanisms in Muscular Dystrophy■

Low Vision Research and Training Center Pennsylvania College of Optometry

Philadelphia, Pennsylvania 19141

Laura A. Edwards, Program Coordinator

The Pennsylvania College of Optometry is coordinating four research projects under a research and demonstration grant from the National Institute of Handicapped Research. The project reports are in section **XIII. Sensory Aids, A. Blindness and Low Vision, 2. Mobility Aids**. They are listed below:

- The Expansion of a Computerized Information System to Assist Researchers and Practitioners in Developing and Evaluating Theories and Aids to Improve Mobility for Individuals with Low Vision. [This project is being carried out at the Eastern Blind Rehabilitation Center, Veterans Administration Hospital, West Haven, Connecticut.]
- Orientation and Mobility of Low Vision Pedestrians. [Research is conducted at the Peabody College of Vanderbilt University, Department of Special Education, Nashville, Tennessee.]
- The Effects of Low Vision Aids and Traditional Versus Nontraditional Training Methods on the Independent Mobility Performance and Stress Levels of Low Vision Individuals. [This project is located at the Pennsylvania College of Optometry.]
- Illumination and Low Vision Mobility. [Research on this project is being carried out at the Pennsylvania College of Optometry.]■

Rehabilitation Engineering Center Southwest Research Institute

San Antonio, Texas 78284

Samuel R. McFarland, Project Director

A report on the Rehabilitation Engineering Center for Product Evaluation will be found in section **XIV. Miscellaneous**■

Center for Advanced Rehabilitation Engineering
University of Texas at Arlington
Arlington, Texas 76019

George V. Kondraske, Ph.D., Director

The University of Texas at Arlington (UTA), the Dallas Rehabilitation Institute (DRI), the University of Texas Health Science Center at Dallas (UTHSCD), and the Dallas Rehabilitation Foundation (DRF) have formed a research consortium that has established the Center for Advanced Rehabilitation Engineering (CARE). Research is intended to develop improved methods for quantification of sensory and motor function in handicapped individuals.

Central to this effort is the computer-automated laboratory system for functional assessment developed in the joint UTA/UTHSCD Biomedical Engineering Program. The computer-automated system includes assessments of mental alertness, vision, hearing, steadiness, reactions, tactile sensations, manual dexterity, speed and coordination, posture, selected activities of daily living, strength, and fatigue. The laboratory is being expanded to include assessments of gait, range of limb motion, and proprioception. The system's utility for assessing the function of handicapped individuals is being evaluated.

The scope and status of these efforts are discussed in the project reports, which are in section **V. Functional Assessment**. They are:

- Development of a Computer-Automated System for Functional Assessment;
- Clinical Evaluation and Application of a Computer-Automated System for Functional Assessment, Part 1; and
- Clinical Evaluation and Application of a Computer-Automated System for Functional Assessment, Part 2■

The Vermont Rehabilitation Engineering Center
University of Vermont
Burlington, Vermont 05405

John W. Frymoyer, M.D., Director

The Vermont Rehabilitation Engineering Center, established in 1983 by a grant from the National Institute of Handicapped Research, takes a multidisciplinary approach to the reduction of disability caused by low back pain through coordinating clinical service with rehabilitation engineering research. The center incorporates a broad-based research program, improved systems of clinical health care and rehabilitation, patient education methods, and evolved methods of information dissemination at local, national, and international levels.

A report describing the work of the Vermont Rehabilitation Engineering Center is in section **XI. Low Back Pain**■

Rehabilitation Engineering Center
University of Virginia
Charlottesville, Virginia 22903

Colin A. McLaurin, Sc.D.
Project Director

The activities of the Rehabilitation Engineering Center have focused on wheelchairs and seating for the disabled during the past year. A report on the progress of the center's projects in this area is in section **IV. Spinal Cord Injury, G. Wheelchairs Including Seating and Controls**, under the title, Wheelchair Research and Development■

Rehabilitation Research and Training Center
University of Virginia Medical Center
Department of Orthopaedics and Rehabilitation
Charlottesville, Virginia 22908

Robert E. McLaughlin, M.D., Director
A. Bennett Wilson, Jr., B.M.S.E., Assistant Director

The Rehabilitation Research and Training Center at the University of Viriginia was initiated in January 1983, by the Department of Orthopaedics and Rehabilitation. Its core areas for study and training are arthritis and low back pain.

The work devoted to arthritis is being carried out in four projects:

- Development of a Biologic Cement for Fixation of Skeletal Implants [in section **III. Total Joint Replacement and other Orthopaedic Implants, A. General**];
- Evaluation of Methods to Measure Locomotion Performance and Activity [in section **VI. Biomechanics, C. Human Locomotion and Gait Training**];
- Assessment of Self-Care Programs for Arthritis

Patients in Rural Settings [in section **X. Arthritis**]; and

• Arthritis Rehabilitation Unit [in section **X. Arthritis**].

The work devoted to low back pain consists of two primary projects, both located in section **XI. Low Back Pain**:

• Chronic Low Back Pain Attitude Survey, and

• Low Back Pain Prevention, Treatment, and High-Risk Inventory Development.

Trace Research and Development Center for the Severely Communicatively Handicapped University of Wisconsin

Madison, Wisconsin 53706

Gregg C. Vanderheiden, M.S., Director

The Rehabilitation Engineering Center at the Trace Research and Development Center is charged with covering a wide variety of topics, including (i) establishing of priority needs for augmentative communication technology; (ii) study of methods for interfacing communication aids used by persons with different disabilities; (iii) improvement of access for severely handicapped individuals to systems and devices, including access to computers, typewriters, and writing systems, and to environmental controls; and, (iv) determination of appropriate devices and techniques for aphasic and other speech-disabled and language-disabled preschool children, and for adults with severe language dysfunction.

Project reports included in this issue are in section **IV. Spinal Cord Injury, E. Communication Methods and Systems for the Severely Disabled**. They are:

• Development of a Unified Quantitative Model for Augmentative Communication;

• Study of Dominant Single Speech Motor Subsystem Dysfunction;

• Cooperative and Commercial Facilitation Projects;

• Developing International Aids Compatability Standards;

• Portable Simple Electronic Transducer and Morse Code Decoder to Serial RS232 Converter;

• Information Resources;

• Access to Computer-Based Services for Persons Unable to Use Current Systems Due to Physical Impairments;

• Keyboard Emulators;

• CRT-Based Headpointing Input Device;

• Comparing Complex Position Averaging Techniques; and

• Adaptation of Standard Tests of Aphasia for Computer-Assisted Administration.

Medical Rehabilitation Research and Training Center for Multiple Sclerosis Albert Einstein College of Medicine Yeshiva University

Bronx, New York 10461

Labe C. Scheinberg, M.D., Principal Investigator; Seymour R. Kaplan, M.D., Co-Principal Investigator

The Medical Rehabilitation Research and Training Center for Multiple Sclerosis of the Albert Einstein College of Medicine was initiated on January 1, 1983, under grant from the National Institute of Handicapped Research. With its inception, the center fulfills the mandate of the National Commission for Multiple Sclerosis which, in 1974, recommended the development of a federally supported research and training center for multiple sclerosis. The recommendation was based on a recognized need for a comprehensive multidisciplinary center with the capability for developing collaborative research projects and for the dissemination of the research findings through its education and training programs.

The mission of the Research and Training Center for Multiple Sclerosis is to conduct research on ways to restore or maintain physical function and retard the disabling effects of multiple sclerosis. The plans for the center's program follow the mandate of federal regulations, which define a core area as "research consisting of a group of related research projects or studies (that) contribute in a complementary way to a centralized body of knowledge of manageable scope."

To fulfill these plans, the initial phase of the center has focused on the implementation of the administrative structure proposed in the Plan of Operation which defines the authority for the clinical and research divisions of the Research and Training Center. A concomitant focus during the initial phase has been the establishment of a coordinated research structure to: (i) develop uniform and systematic procedures for the assessment of all multiple sclerosis patients accepted for the center's research projects; and, (ii) develop a data base management information system necessary for the effective implementation of the evaluation plan.

The hallmark of the center is a partnership of neurology, rehabilitation medicine, and psychiatry, collaborating on an integrated program of research and education in order to develop effective strategies for dealing with the consequences of multiple sclerosis. The program of the center consists of a broad range of laboratory, behavioral, and clinical research in chronic neurological illness.

Among the research projects operating under the aegis of the center are the following:

1. The development of standardized measures of functional disability in multiple sclerosis.
2. The use of radioisotopes as a noninvasive assessment procedure for neurogenic bladder dysfunction.
3. The value of physical therapy for improvement of gait.
4. An analysis of the effects of aerobic exercise in multiple sclerosis.
5. Evaluation of innovative job placement strategies.
6. Secondary analysis of RSA-300 data.
7. Evaluation of outpatient treatment for severely disabled patients.
8. Effects of abnormal interferon production.
9. Lymphocyte markers of disease activity in multiple sclerosis.

Progress during the past year has been significant. Implementation of the center's program of research has proceeded far enough to allow considerable data analysis in most projects. Dissemination of these findings has taken place as quickly as possible. One center project, the Development of Standardized Measures of Functional Disability, has already had significant international impact. The center was responsible for the field testing of the Minimal Record of Disability (MRD) in the United States and Canada. To date, more than 400 patients in 12 major medical centers in North America have been evaluated. The MRD has become a standard portion of the assessment in most new studies of multiple sclerosis. Beginning in July 1984, a national collaborative double-blind clinical trial of cyclosporine (an immunosuppressive) will use the MRD as a major part of its measurement component. Researchers interested in other chronic disorders have made inquiries to the center concerning their desire to adapt the MRD to chronic illness in general.

In the coming years, the center will look toward further refinements in its research program and exploration of new areas of investigation. A particular emphasis will be placed on collaborative studies pooling the resources of several different disciplines and institutions, and generalization of findings to chronic disabling illnesses other than multiple sclerosis■

Department of Health and Human Services

National Institute of General Medical Sciences

Physiology and Biomedical Engineering Program
Bethesda, Maryland 20205

Leo H. von Euler, M.D., Acting Director
Marvin Cassman, Ph.D., Acting Chief, Biomedical Engineering and Instrument Development Section
Americo Rivera, Jr., Ph.D. Program Administrator

Four project reports sponsored by the National Institute of General Medical Sciences (NIGMS) are included in this issue. They are:

- Myoelectric Controls for Orthotic and Prosthetic Systems, in section **I. Amputations and Limb Prostheses, C. Upper Limb, 1. General**;
- Head/Neck/Upper Torso Response to Dynamic Loading;
- The Traumatology of the Head and Neck, both in section **VI. Biomechanics, B. Spine**; and
- Flexible Glow Discharge Polymer Leaching Barriers, in section **XIV. Miscellaneous**■

Liberty Mutual Insurance Company

The NeuroMuscular Research Center
Boston University
Boston, Massachusetts 02215

Carlo J. De Luca, Ph.D., Director

The NeuroMuscular Research Center's efforts have for several years focused on five general areas:

Studies on muscle contraction include several investigations toward understanding how the central

nervous system controls individual muscles and groups of muscles in different types of contractions.

A second group of studies focuses on muscle fatigue. This research has continued for the past 6 years and involves developing and testing a technique for objectively measuring the fatigue rate of contracting muscles.

The third area of interest is clinical rehabilitation. For the past 5 years, the laboratory has been developing a new technique for improving the quality and quantity of joint movements among patients affected with muscle hypertonicity. The technique involves modulation of the skin's sensory input by applying topical anesthesia.

In the fourth area, prosthetics control, a recording electrode is being developed, which may be implanted around a severed peripheral nerve. Its purpose is to continuously detect distinguishable signals associated with functionally distinct limb movements.

Work in the fifth area is concerned with instrumentation. Some of the techniques and instruments the laboratory designs, evaluates, and refines are specific to one of the other four areas, and reports on these will be found in the section to which they pertain.

Project reports included in this issue are:

- Long-Term Recording of Voluntarily Elicited Nerve Signals, in section **I. Amputations and Limb Prostheses, C. Upper Limb, 1. General.**

The following reports are in section **VIII. Properties of Muscles**:

- Surface Electrode for Detecting Myoelectric Signals;
- The Myoelectric Signal Decomposition Technique;
- The Common Drive Concept;
- The Control of Individual Muscles: Relationship Between Firing Rate and Recruitment;
- Synchronization of Motor Unit Discharges;
- The Control of Antagonist Muscles During Contraction;
- The Control of Synergist Muscles During Contraction;
- Muscle Fatigue and the Myoelectric Signal;
- Muscle Fatigue Differences Due to Handedness and Gender;
- The Muscle Fatigue Monitor; and
- The Estimation of Muscle Fiber Conduction Velocity.

The remaining reports are in section **XIV. Miscellaneous**:

- Topical Anesthesia and Muscular Hypertonicity;
- Topical Anesthesia and Parkinson's Disease; and
- Topical Anesthesia with Normal Subjects■

National Institutes of Health

National Institute of Neurological and Communicative Disorders and Stroke Neural Prosthesis Program

Bethesda, Maryland 20205

F. Terry Hambrecht, M.D., Head
Neural Prosthesis Program

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) Neural Prosthesis Program is composed of investigators whose main objective is the solution of fundamental neuroscience and technological problems that are preventing the development of aids to replace function in the neurologically handicapped. Although some prototype clinical testing is carried out by the program, most clinical testing of neural prostheses is supported by other NINCDS programs and by other government agencies. The principal prostheses being developed are multichannel cochlear prostheses for the deaf, motor prostheses for the paralyzed, and bladder evacuation prostheses for individuals with neurogenic bladders. Each of these prostheses has been demonstrated to be feasible, but must be perfected before large-scale clinical acceptance will occur. Such perfection includes the development of safer and more effective electrodes, the development of improved biomaterials specifically formulated for the prosthetic application, the development of implantable stimulators under closed-loop control, the design and fabrication of artificial transducers to interface with closed-loop control systems, etc.

The project reports in this issue are representative of the research and development work that presently is being supported.The following reports are in section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 1. General**:

- Development and Evaluation of Safe Methods of Intracortical and Peripheral Nerve Stimulation;
- Development of Neural Stimulating Electrodes and Evaluation of their Electrochemical Reactions;
- Artificial Sensory Transductors;
- Adhesion Studies Program;
- Ion-Exchange Stimulation Electrodes;
- Capacitor Stimulating Electrodes for Activation of Neural Tissue;
- Capacitor Stimulating Electrodes for Activation of Neural Tissue; and
- Multichannel Multiplexed Intracortical Recording Arrays.

In section **IV., I., Functional Electrical Stimulation, 2. Upper Limb Applications**:
- Closed-Loop Control of Electrically Stimulated Muscle.

In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**:
- Speech Processors for Auditory Prostheses.

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases Musculoskeletal Diseases Program
Bethesda, Maryland 20205

Stephen L. Gordon, Ph.D., Director Musculoskeletal Diseases Program

Project reports of rehabilitation related research supported by the Musculoskeletal Diseases Program of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, a bureau of the National Institutes of Health, contained in this issue follow.

In section **III. Total Joint Replacement and other Orthopaedic Implants, A. General**:
- Diagnosis of Loose or Damaged Total Joint Replacement;
- Cementless Hip and Knee Prostheses;
- Mechanisms of Orthopaedic Implant Loosening;
- Bacterial Colonization of Surgical Biomaterials;
- In Vitro and In Vivo Corrosion of Orthopaedic Implants; and
- Intermediate Organometallic Corrosion Products.

In section **III., B. Hip**:
- Vascular Responses to Hip Replacements, and
- Total Surgical Replacement of the Human Hip Joint.

In section **III., C. Knee**:
- In Vivo Loading on Total Knee Joints, and
- Biomechanical Study of Total Knee Replacement.

In section **V. Functional Assessment**:
- Epidemiology of Physical Activity.

In section **VI. Biomechanics, A. Joint Studies, 1. General**:
- Joint Contracture: Biomechanical Correlates, and
- Biomechanics of Ligament/Tendon Repairs and Grafts.

In section **VI., A. Joint Studies, 2. Lower Limb**:
- Clinical Biomechanics of the Knee Rotation Laxities;
- Ligamentous Knee Stability Combined Clinical Loadings;
- Biomechanics of the Hip and Knee;
- Mechanics of Human Acetabulum;
- Biomechanics of Anterior Cruciate Repairs; and
- Proximal Femur Load Transmission in Early Childhood.

In section **VI., A. Joint Studies, 3. Upper Limb**:
- Functional Forces in Normal and Abnormal Fingers;
- Static Force and Stability Analysis of Human Elbow;
- Biomechanics of the Wrist; and
- Biomechanical Study of the Radial-Ulnar-Carpal Joint.

In section **VI., C. Human Locomotion and Gait Training**:
- Control of Human Locomotion;
- Locomotion Idling Metabolism and Gait Dynamics;
- Medical Gastrocnemius Muscle Function in Locomotion; and
- Development of a Clinically Applicable Model of Gait.

In Section **VI., D. Upper Limb Function**:
- Processes Underlying Arm Trajectory Formation.

In section **VI., E. Other**:
- Human Response and Lower Extremity Injury.

In section **VII. Wound and Fracture Healing**:
- Studies of Factors Affecting Orthopaedic Infections;
- Effects of Immobilization and Motion in the Injured Tendon; and
- Flexor Tendon Healing: Restoration of the Gliding Surface.

In section **VIII. Properties of Muscle**:
- Control of Muscle Protein Metabolism During Exercise;
- Adaptation of Muscle to High Resistance Exercise;
- Skeletal Muscle Adaptations Induced by Training; and
- Origin of Limb Position and Movement Signals in Humans.

In section **IX. Ligaments and Tendons**:
- Ligament Proteoglycans and Interactions with Collagen; and
- Development of Synthetic Replacement Fibro-Osseus Pulleys.

Northwestern University Rehabilitation Engineering Program

Prosthetics Research Laboratory
Chicago, Illinois 60611

Dudley S. Childress, Ph.D., Director
Edward C. Grahn, Associate Director

The Rehabilitation Engineering Program at Northwestern University has sponsored the following projects reported in this issue:

In section **I. Amputations and Limb Prostheses, C. Upper Limb, 1. General**:
- Myoprocessor NU 110;
- Myoprocessor NU 112;
- Myotrode NU 126; and, in **2. Below Elbow**,
- Below-Elbow Prosthesic System.

In section **II. Orthotics, A. Lower Limb**:
- Design and Evaluation of a Knee Orthosis.

In section **III. Total Joint Replacement and other Orthopaedic Impants, A. General**:
- Evaluation and Development of Biomaterials Used in Total Joint Replacement;
- Investigation of the Bone/Bone Cement/Implant Interface Formed by Total Joint Replacement; and
- Structural Analysis of Total Joint Replacement.

In section **III., C. Knee**:
- Interaction of Total-Knee Replacement Geometry with Knee Ligaments; and
- Prospective Clinical Study of the Kinematic Knee Design.

In section **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**:
- MICRODEC II: Environmental Control System and Computer Access Aid■

Royal Commonwealth Society for the Blind

Haywards Heath
West Sussex RH16 3AZ, England

A.W. Johns, O.B.E., Director

The Royal Commonwealth Society for the Blind has contributed a description of The Positive Braille Writer, a new form of positive braille writing equipment for particular use in developing countries. The project report is in section **XIII. Sensory Aids, A. Blindness and Low Vision, 3. Reading Aids**■

Royal Ottawa Regional Rehabilitation Centre Rehabilitation Engineering Department

Ottawa, Ontario, K1H 8M2, Canada

Michael D. O'Riain, Ph.D., Director of Rehabilitation Engineering

The Rehabilitation Engineering Department of the Royal Ottawa Regional Rehabilitation Centre (RORRC) is a teaching facility of the University of Ottawa. In addition to its inpatient facilities and its extensive outpatient services, the centre is involved in the coordination, administration, and planning of rehabilitation programs on a regional basis.

Other available services provided by the centre include: prosthetics and orthotics, leisure services, pulmonary assessment, outpatient clinics, communication disorders, psychology, vocational evaluation, physiotherapy, driving evaluation, funding assistance, community services, education, social work, and occupational therapy.

Services provided by Rehabilitation Engineering fall into three main categories:

1. The operation of specialized diagnostic services.
2. Research, development, and construction of innovative aids for handicapped persons.
3. Performance of investigative research.

The specialized diagnostic services operated by Rehabilitation Engineering include a Gait Laboratory, an Infra-red Thermography system, and the administration of an EMG clinic. Research, development, and construction of special aids is performed in association with personnel from occupational therapy, physiotherapy, communication disorders, social work,

prosthetics and orthotics, nursing, psychology, and also in association with psychiatrists. Rehabilitation Engineering also performs research and development for special aids on projects initiated within the department itself. Investigative research is generally performed by an interdisciplinary research team. Some research projects are initiated by personnel in other departments and some are initiated within Rehabilitation Engineering.

Among the projects conducted over the past year are the following:

A Wheelchair Brake Alarm—This is a device that alerts the wheelchair user if a transfer is being attempted without the brakes applied. It is currently undergoing testing by staff at RORRC.

A New Lift Assist—This design produces motion by an axle and a sliding mechanism. The lifting force is achieved by two sets of passive springs. The frame and most of the components are made of strong, lightweight aluminium; the seat can be locked in the folded position for carrying. The lift assist is being evaluated in use by patients at the centre.

New Footswitches for Gait Analysis—This new footswitch provides almost total absence of compliance (which can cause delays both in closing and in opening timing), springiness of materials used, and special precautions to prevent lead breakage. Equally important is a lip on the outside of each footswitch to ensure that switch closure occurs in all types of pressure situations.

A Rate-Dependent Limb Load Monitor—This system was developed to give patients biofeedback training in achieving an appropriate rate of weight acceptance and to produce a permanent record of their performance.

Biofeedback in Ankle Re-Education of Stroke Patients—This is a study to evaluate the efficacy of ankle position biofeedback and rhythmic practice as compared with more traditional EMG biofeedback and a no-treatment control. This treatment approach measures ankle position through the use of an electrogoniometer.

EMG and Limb Strength—The goal of this study is to devise a systematic method for relating measured changes in EMG parameters to changes in limb strength. Work has involved measurements of EMG from the vastus medialis and vastus lateralis muscles during walking.

A Microprocessor-Controlled Electric Feeder—This feeder, which is intended for paralyzed persons who could not otherwise feed themselves, will feature artificial vision as well as a microprocessor controller. The artificial vision enables the user to optically sense the shape of food and its position on a plate prior to attempting to pick it up.

Motor Soccer—A team game for persons of all ages who use electric wheelchairs to be played on a basketball court■

Scottish Home and Health Department and Tayside Health Board Dundee Limb Fitting Centre

Dundee DD5 1AG, Scotland

G. Murdoch, Surgeon in Charge
D.N. Condie, Senior Rehabilitation Engineer

Four rehabilitation engineering projects conducted at the Dundee Limb Fitting Centre are included in this issue. Three of these projects are funded by the Scottish Home and Health Department. They are:

- An Investigation into the Mobility of the Cerebral Palsied Child, in section **II. Orthotics, A. Lower Limb**;
- Modular Seating for Children; and
- Modular Seating for the Elderly, both in section **IV. Spinal Cord Injury, G. Wheelchairs Including Seating and Controls**.

The fourth report, funded by the Tayside Health Board is:

- Assessment of Hand Function and the Development of Wrist-Hand Orthoses, in section **II. Orthotics, B. Upper Limb**■

Smith-Kettlewell Institute of Visual Sciences

Rehabilitation Engineering Center
Medical Research Institute of San Francisco
Pacific Medical Center
San Francisco, California 94115

Arthur Jampolsky, M.D., Director
John Brabyn, Ph.D., Co-Director
Deborah Gilden, Ph.D., Associate Director

The Smith-Kettlewell Institute Rehabilitation Engineering Center specializes in the development of sensory aids, particularly for the blind. During the past year, emphasis has been placed on the research utilization phase of many projects to ensure maximum impact on the target population.

The research program is divided into the following main categories: vocational rehabilitation engineering, orientation and mobility research, low vision research, communication aids, and educational aids. Activities in the areas of training, evaluation, and information dissemination also have been undertaken.

Vocational Rehabilitation Engineering—A highlight of the vocational program has been the completion of the first microprocessor-based vocational aid (a talking telephone switchboard monitor). This system allows a blind operator to monitor and direct incoming calls on a 30-line switchboard. The system, with speech readout, is successfully being used in a local bank. Software can be easily adapted for larger switchboards, and work is underway to investigate methods of improving or bypassing the mechanical switch overlay used to monitor the incoming lines, so that replication and adaptation to other switchboards can be performed easily.

Other new vocational instruments developed for use by the blind are a braille dial maker, a speaker phase tester, a piano tuning aid, an auditory carpenter's level, a soldering aid, and an audio capacitance bridge. Several vocational aids entered commercial production, including a receptionist mat and a liquid level indicator. Another project involved the modification of a thermoform machine to allow for more efficient operation when producing large numbers of copies.

Other Research Projects—Orientation and mobility research have included the installation of a demonstration talking sign system in two campuses of the San Diego Community College system. Development of a rigid collapsible cane prototype also was completed.

In the low vision research program, development of inexpensive spectacles for people in Third World countries was begun. The viewscan text system was evaluated. Studies were completed on mobility and dark adaptation in ARM patients, and effects of glare on low contrast acuity in cataract patients were measured. The pediatric program included studies of visual acuity development in normal and premature infants, the application of a new screening system in diagnosing ocular disorders, and a comparison of different methodologies of acuity measurement. In the geriatric program, data has been gathered on vestibulo-ocular reflexes in the blind and mathematical models have been developed.

A new educational aid, the Animated Auditory Reinforcing Feedback (AARF) form board was developed and evaluated. An auditory arcade was evaluated in school settings, and desirable modifications identified. An exercise cycle speedometer for the blind also was developed.

Communication aids research has included evaluation of the VersaBraille, the Microbrailler, the Echo II speech synthesizer, and the Cranmer Modified Perkins Brailler. The new Oculo-Encephalographic Communication System was substantially improved, and a simplified demonstration version developed. An improved tactile paging system for the deaf and deaf-blind was completed, and residential evaluation of the HKNC Tactile Communicator was begun. Commercialization of the Holmlund/Alden Vibrotactor has been arranged, and development of a portable version of the Teletactor (a tactile-output speech encoder for deaf children) is nearing completion■

Speech Transmission Laboratory
Royal Institute of Technology

S-100 44 Stockholm, Sweden

Gunnar Fant, Director

The Speech Transmission Laboratory is a research function of the Royal Institute of Technology and projects conducted there receive support from the

following: Swedish Board for Technical Development, the Bank of Sweden Tercentenary Foundation, The Swedish Council for Research in the Humanities and Social Sciences, the Swedish Natural Science Research Council, and The Swedish Council for Planning and Coordination of Research.

Included in this issue of the project reports is Bliss Symbol-to-Speech Conversion: "Blisstalk," in section **IV. Spinal Cord Injury, E. Communication Methods and Systems for the Severely Disabled**.

University College London Department of Mechanical Engineering Bioengineering Centre

London SW15 5PR, England

R.M. Davies, Ph.D., Director

A comprehensive program of research and development of prosthetic methods has been carried out over a number of years by the Bioengineering Centre, which is part of the University College London. The philosophy has been to distill the expertise of the artisan into specially developed automated systems. This has led to the introduction of microprocessor controls and computer-aided design techniques into this area of prosthetics. Part of the rationale is to use computer techniques to determine the prosthetic requirements of patients, and then to computer-control the automated machines that fabricate the prostheses. Later advances in the state of the prosthetic art would, theoretically, mean simple updating in software.

A project report on a computer aided design (CAD) is included in this issue. It is titled Successful Application of CAD Automation to the Production of Individual Prostheses, and is in section **1. Amputations and Limb Prostheses, A. General**.

University of Strathclyde Bioengineering Unit Wolfson Centre

Glasgow G3 ONW, Scotland

J.P. Paul, Head of Department

Seven projects conducted by the Bioengineering Unit are included in this issue. They are:

- Biomechanical Assessment of Patients Treated by Joint Surgery, in section **III. Total Joint Replacement and other Orthopaedic Implants, B. Hip**;
- Evaluation of Joint Loadings in the Use of Walking Aids in Total Hip Replacement and
- Ankle Biomechanics, both in section **VI. Biomechanics, A. Joint Studies, 2. Lower Limb**;
- The Role of Abdominal Muscles in Stabilizing the Spine in Flexion: The Mechanics of Force Transmission,
- The Detailed Anatomy of the Vertebral Attachments of the Thoracolumbar Fascia and Its Functional Implications, and
- The Morphological Changes in the Lumbar Foramina in Normal and Abnormal Motions Segments After Distraction, all in section **VI., B. Spine**; and
- A Study of Intertrochanteric Fracture Fixation Methods, in section **VII. Wound and Fracture Healing**.

Veterans Administration Rehabilitation Research and Development Service

Department of Medicine and Surgery
Washington, D.C. 20420

Margaret J. Giannini, Director

The Rehabilitation Research and Development Service of the Veterans Administration sponsors investigative projects dealing with the rehabilitation and support of handicapped veterans in order to improve the quality of their lives and to enhance their functional independence. Projects focus on devices and prototype development which relate particularly to amputations and limb prostheses, spinal cord injury, and sensory aids. Development and evaluation of sponsored projects require compliance with the medical device laws and regulations of the U.S. Govern-

ment, including those of the Food and Drug Administration and other federal agencies that monitor applicable aspects of safety.

The VA cooperates closely with federal, state, and local governmental and nongovernmental organizations by jointly funding projects in rehabilitation research and development. In the past, merit reviewed and approved projects of the Rehabilitation Research and Development Service have been cosponsored with such agencies as the Department of Health and Human Services, the Department of Education, universities, and veterans service organizations.

The Rehabilitation Research and Development Service encourages researchers to submit proposals for scientific merit review. Proposals are reviewed biannually, in April and October. Guidelines on procedural instructions for submitting proposals are available from the Rehabilitation Research and Development Service, VA Central Office, 810 Vermont Avenue, N.W., Washington, D.C. 20420.

Projects included in this issue follow:

Veterans Administration Medical Center Birmingham, Alabama 35233

In section **IV. Spinal Cord Injury, E. Communication Methods and Systems for the Severely Disabled**:

• Efficacy of Remote Delivery of Aphasia Treatment by TEL-Communicology.

Veterans Administration Medical Center Tuscon, Arizona 85723

In section **I. Amputations and Limb Prostheses, A. General**:

• Comprehensive Management of Upper and Lower Extremity Amputation.

In section **IV. Spinal Cord Injury, B. Medical Treatment**:

• Residual Bladder Volume Determination for Spinal Cord Injury Patients.

Veterans Administration Medical Center Little Rock, Arkansas 72206

In section **IV. Spinal Cord Injury, B. Medical Treatment**:

• Development of Analytical and Laboratory Models of the Bladder and Urinary Tract.

In section **V. Functional Assessment**:

• The Efficacy of Surgical and Rehabilitative Procedures of the Knee.

In section **XIII. Sensory Aids, C. Speech Impairment**:

• Tongue Initiated Speech Prosthesis for the Laryngectomy Patient.

University of California, San Diego Medical Center 92110, and Veterans Administration Hospital La Jolla, California 92161

In section **III. Total Joint Replacement and other Orthopaedic Implants**:

• Implant Fixation by Post-Insertion Pressurization of Polymethylmethacrylate.

Veterans Administration Medical Center Loma Linda, California 92357

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 2. Below-Knee**:

• Optimum Prosthetic Foot Characteristics for Dysvascular Below-Knee Amputees.

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 4. Other**:

• Weight Transfer Training Using Biofeedback and Electrical Stimulation in Strokes and Incomplete Spinal Cord Transections.

Wadsworth Veterans Administration Medical Center Los Angeles, California 90073

In section **III. Total Joint Replacement and other Orthopaedic Implants, B. Hip**:

• Total Hip Implant Biotelemetry.

Veterans Administration Medical Center Martinez, California 94553

In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**:

• A Psychophysical Model to Characterize Sensorineural Hearing Loss, and

• An Electrotactile Aid for Treating Sensorineural Hearing Loss and Aphasia.

Veterans Administration Medical Center Palo Alto, California 94304

In section **IV. Spinal Cord Injury, A. General Rehabilitation**:

- Interactive Video Education System for Rehabilitation.

In section **IV, F. Environmental Control Systems for the Severely Disabled**:

- Development and Evaluation of a Robotic Aid for the Severely Disabled Individual;
- Design of a Six-Axis Joystick for a Robotic Manipulation Aid;
- Sensor and Gripper Development for the Robotic Aid Project;
- Interactive Voice Studies and the Design of Command Vocabularies for Voice-Controlled Systems;
- The Study of Manipulator Motion Under Constraint;
- Evaluation of the Human/Machine/Environment Triad: An Interactive Model Applied to the Robotics Aid Project; and
- Ultrasonic Head Control Unit.

In section **IV, G. Wheelchairs, Including Seating and Controls**:

- Integrated Wheelchair Technology Tested;
- Wheelchair Feedback Controllers;
- Images Project; and
- Seating System for Body Support and Prevention of Tissue Trauma.

In section **V. Functional Assessment**:

- Quantitative Evaluation of Nerve Repair.

In section **VI. Biomechanics, B. Spine**:

- Mechanical Analysis of Cervical Spine Stabilization Techniques.

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 3. Reading Aids**:

- Development of a Graphic Braille Display, and
- Development of a Hand-Guided Reading Aid for the Visually Impaired.

In section **XIV. Miscellaneous**:

- A Life-Span Approach to Product Design and Development for the Aging Population, and
- Rehabilitation Information Project.

Veterans Administration Medical Center San Diego, California 92161

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 2. Below-Knee**:

- Volume Changes Occuring in Postoperative Below-Knee Amputees, and
- Analysis of Below-Knee Suspension Systems: Effect on Gait.

In section **VI. Biomechanics, E. Other**:

- Foot Interface Pressure Study.

In section **VII. Wound and Fracture Healing**:

- Effect of Stress and Motion on Repair of Hard and Soft Tissues.

Veterans Administration Medical Center San Francisco, California 94121

In section **III. Total Joint Replacement and other Orthopaedic Implants, B. Hip**:

- The Efficacy of Radiolucent Low Modulus Total Hip Surface Replacement.

Veterans Administration Medical Center Denver, Colorado 80220

In section **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**:

- Ocular Controlled Communication and Environmental Control for Severely Disabled Veterans.

Veterans Administration Medical Center Gainesville, Florida 32602

In section **III. Total Joint Replacement and other Orthopaedic Implants, B. Hip**:

- Quantitative Analysis of the Effect of Total Hip Arthroplasty on Stress and Strain in the Human Pelvis.

In section **XIV. Miscellaneous**:

- Foreign Body Reaction in the Lung to Intravenously Injected Biomaterials.

Veterans Administration Medical Center Atlanta, Georgia 30033

In section **IV. Spinal Cord Injury, E. Communication Methods and Systems for the Severely Disabled**:

- A Unique Comprehensive Communication System for Speech-Impaired Persons.

In section **IV, G. Wheelchairs, Including Seating and Controls**:

- Manual Wheelchair with Anti-Rollback Wheel, and
- Alternate Transit Vehicle for the Physically Disabled Person.

In section **IV, H. Personal Licensed Vehicles**:
- A Driving Simulator for the Physically Handicapped Person.

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 2. Mobility Aids**:
- The VA Guide Dog Harness, and
- SONA/SONA-ECS.

In section **XIII, A. Blindness and Low Vision, 3. Reading Aids**:
- A Large Print Word Processor for the Visually Impaired Person, and
- Musical Language and Large Print Consideration in Human Factors Engineering.

Veterans Administration Medical Center Augusta, Georgia 30910

In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**:
- Acoustic Feedback Suppression in Hearing Aids.

Veterans Administration Medical Center Decatur, Georgia 30033

In section **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**:
- Design and Evaluation of Showers and Bathing Fixtures for Disabled and Elderly Veterans.

Veterans Administration Medical Center Hines, Illinois 60141

In section **IV. Spinal Cord Injury, B. Medical Treatment**:
- Neural Mechanisms Underlying Bladder Dysfunction After Spinal Trauma.

In section **VI. Biomechanics, B. Spine**:
- Biomechanical Study of Spinal Fusion and Its Effect on the Free Segments.

In section **XIII. Sensory Aids, A. Blindness and Low Vision, 1. General**:
- Predicting the Visual Abilities of Partially Sighted Persons, and
- A Study of the Effectiveness of a Blind Rehabilitation Program.

In section **XIII, A. Blindness and Low Vision, 2. Mobility Aids**:
- The Effects of Preview Distance on the Mobility of the Blind Pedestrian, and
- Measuring the Mobility of Blind Travelers.

Veterans Administration Medical Center New Orleans, Louisiana 70112

In section **III. Total Joint Replacement and other Orthopaedic Implants, A. General**:
- The Mechanical Properties of Porous-Coated Orthopaedic Alloy, and
- Retrieval and Analysis of Orthopaedic Implants.

Johns Hopkins University Applied Physics Laboratory Laurel, Maryland 20707

In section **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**:
- Wheelchair Control and Robot Arm/Work Table System for High Spinal Cord Injured Persons.

Veterans Administration Medical Center West Roxbury, Massachusetts 02132

In section **II. Orthotics, A. Lower Limb**:
- A Motion-Guiding Load-Bearing External Frame for the Knee.

In section **III. Total Joint Replacement and other Orthopaedic Implants, C. Knee**:
- Investigation of a Simplified Internal Knee Prosthesis.

Veterans Administration Medical Center Bronx, New York 10468

In section **IV. Spinal Cord Injury, F. Environmental Control Systems for the Severely Disabled**:
- Capuchin Monkeys as Aides for Quadriplegics.

Veterans Administration Medical Center Castle Point, New York 12511

In section **III. Total Joint Replacement and other Orthopaedic Implants, A. General**:
- Biomechanics of Bone Resorption/Regeneration at a Bone-Implant Interface.

In section **VII. Wound and Fracture Healing**:
- Stimulation of Repair of Cortical Bone Transplants by Implantation of Piezoelectric Materials.

In section **XIV. Miscellaneous**:
- A Program for Evaluation and Monitoring of the Dysvascular Patient.

Case-Western Reserve University
Cleveland, Ohio 44109

In section **II. Orthotics, B. Upper Limb**:
• Sensory Substitution System for Grasp Force and Hand Position Feedback.
In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 2. Upper Limb Applications**:
• Restoration of Upper Limb Function Using Functional Electrical Stimulation (FES).

Veterans Administration Medical Center
Cleveland, Ohio 44106

In section **III. Total Joint Replacement and other Orthopaedic Implants, A. General**:
• Late Loosening in Total Joint Replacement in the Lower Extremities.
In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 3. Lower Limb Applications**:
• Walking Restored in Paralyzed Man Using Electronic Orthotics.
In section **XIV. Miscellaneous**:
• Microsurgical Techniques Applied to Orthopaedic and Hand Surgery.

Veterans Administration Medical Center
Dayton, Ohio 45428

In secton **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 4. Other**:
• Fitness Improvements and Physiological Responses to FES Exercise.

Wright State University School of Medicine
Dayton, Ohio 45435

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 4. Other**:
• Active Physical Therapy: Application of FES to Rehabilitation Medicine.

Veterans Administration Medical Center
Philadelphia, Pennsylvania 19104

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 3. Above-Knee**:
• Myoelectrically Controlled Above-Knee Prosthesis: A Pilot Study.

University of Pittsburgh
Pittsburgh, Pennsylvania 15260

In section **III. Total Joint Replacement and other Orthopaedic Implants, A. General**:
• Study of Wear Particle Analysis in Human Artificial Joints.

Veterans Administration Medical Center
Columbia, South Carolina 29201

In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**:
• Investigation of Acoustic Reflex in Elderly Persons.

Veterans Administration Medical Center
Nashville, Tennessee 37203

In section **VI. Biomechanics, A. Joint Studies, 2. Lower Limb**:
• Pathokinesiology of Anterior Cruciate Ligament Deficiency.
In section **VI, C. Human Locomotion and Gait Training**:
• Feature Extraction for EMG Gait Analysis.
In section **VI, E. Other**:
• Bone In Vivo and In Vitro Stress and Strain Patterns.
In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**:
• The Modulation Transfer Function as a Predictor of Speech Intelligibility.

Veterans Administration Medical Center
Dallas, Texas 75216

In section **VIII. Properties of Muscle**:
• Myoelectric Assessment of Human Lumbar Muscle Function.

Veterans Administration Medical Center
Houston, Texas 77211

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 1. General**:
• Automated Fabrication of Lower Extremity Prosthetic Sockets.

Veterans Administration Medical Center Temple, Texas 76501

In section **IV. Spinal Cord Injury, B. Medical Treatment**:

• The Bio-Feedback Incontinence-Training Program.

In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**:

• Development of a Digital Hearing Aid and Fitting Procedure, and

• Effects of Auditory Cues in Computer-Assisted Instruction in Lipreading.

Veterans Administration Medical Center Salt Lake City, Utah 84148

In section **IV. Spinal Cord Injury, I. Functional Electrical Stimulation, 4. Other**:

• Influence of Sural Nerve Stimulation on Motor Unit Control in Normal Subjects and Those with Spastic Paresis.

Veterans Administration Medical Center Richmond, Virginia 23249

In section **XIII. Sensory Aids, B. Deafness and Hearing Impairment**:

• Changes in Frequency Organization of the Cochlea During Aging.

University of Washington Department of Orthopaedics Seattle, Washington 98195

In section **VII. Wound and Fracture Healing**:

• Transcutaneous Oxygen Tension as Predictor of Wound Healing.

Veterans Administration Medical Center Seattle, Washington 98108

In section **I. Amputations and Limb Prostheses, B. Lower Limb, 1. General**:

• The VA SEATTLE Foot.

In section **I, B. Lower Limb, 2. Below-Knee**:

• Evaluation of Physiologic Suspension Factors in Below-Knee Amputees.

In section **III. Total Joint Replacement and other Orthopaedic Implants, A. General**:

• Evaluation of Total Joint Loosening Using X--Ray Photogrammetry.

In section **IV. Spinal Cord Injury, B. Medical Treatment**:

• H Reflex Changes Following Spinal Cord Injury.

In section **VII. Wound and Fracture Healing**:

• Morphological and Clinical Studies of Microwounds in Ischemic Human Tissues.

Veterans Administration Medical Center Wood (Milwaukee), Wisconsin 53191

In section **VI. Biomechanics, C. Human Locomotion and Gait Training**:

• Studies of Normal and Abnormal Motion.

Waseda University Department of Science and Engineering

Tokyo, Japan

Koichi Koganezawa and Ichiro Kato, Principal Investigators

An above-knee prosthesis to improve walking ability has been developed at the Department of Science and Engineering laboratory of Waseda University. A project report, The Development of an Above-Knee Prosthesis Adaptable to a Voluntary Walking Period, is included in this issue in section **I. Amputations and Limb Prostheses, B. Lower Limb, 2. Above-Knee**.

Welfare Equipment Development Center

The University of Tokyo Department of Precision Machinery Engineering
Bunkyo-ku, 113 Tokyo, Japan

Kohnosuke Tomabechi, Chief Director

The Welfare Equipment Development Center, since its establishment in 1976, has distributed information

on the uses of welfare equipment to disabled people and to public welfare organization staff throughout Japan, and has been conducting research for improvement, experimental production, and evaluation of the equipment.

The objective of the project launched last year under the professional advice of the Ministry of Health and Welfare, and sponsored by the Tokyo Masonic Association, has been to collect data on patients in hospitals, rehabilitation centers, and various welfare facilities. Together with research findings from universities, organizations, and businesses, this data will form a publication for use by researchers and users of the equipment involved.

A year before its start in Japan, this project was initiated by the Nordic Committee, a group composed of five north European nations.

The welfare equipment research project covers a wide range of subjects that includes: deaf, deaf-blind, and speech handicapped; prostheses, orthoses, mobility aids, communication aids, domestic aids, and treatment; mental retardation; methodology, technical, and functional testing and adaptation of aids; needs analyses; housing and community planning, including public transportation; work environment and work aids; and, general social and psychological aspects of treating disabled people■

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